

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

BETTY ANN MARSEE,
Administratrix of the Estate
of MARVIN SEAN MARSEE,
Deceased,

Plaintiff,

vs.

UNITED STATES TOBACCO CO.,
a New Jersey corporation,

Defendant.

No. Civ-84-2777R

TRANSCRIPT OF JURY TRIAL PROCEEDINGS
Wednesday, June 11, 1986

A p p e a r a n c e s:

HON. DAVID L. RUSSELL,
U.S. District Judge, Presiding

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Volume 28

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Appeared for Defendant.

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BE IT REMEMBERED, that on the 11th day of June, 1986, the above matter coming on for jury trial before the Honorable David L. Russell, United States District Judge for the Western District of Oklahoma, and the parties appearing in person and or by counsel as hereinabove set forth, the following proceedings were had:

AFTERNOON SESSION

Wednesday, June 11, 1986

THE COURT: Be seated. You may resume the stand.

Q. (BY MS. DESCHAMPS-BRALY) Miss Marsee, before we went to lunch, we were talking about your brother's last days. Let me backtrack you a little bit, and let's talk about your mother. How did your mother react to Sean's illness?

A. She dealt with it the best way she could.

Q. Was your mother working during the time that Sean was sick?

A. She had to.

1 Q. What would she do when she would come home
2 from work?

3 A. She would give Sean a bath in the mornings.
4 She worked nights. She would give Sean a bath in the
5 mornings, and tears -- she would cry. She would be
6 very emotional and she would say, "I just don't know
7 how much more he can take."

8 Q. Did your mother ever cry in front of Sean?

9 A. She tried not to upset him because he knew
10 when she cried; he was upsetting her, and he didn't
11 mean to upset her.

12 The Friday that -- the Friday morning when
13 she came home, she was going to give him a bath, but
14 he was too weak and we couldn't get him out of bed to
15 give him a bath. And mom told us to sponge him down
16 from now on and not give him a bath.

17 Q. Did there come a time when you realized that
18 your mother was having some problems that you did not
19 notice before?

20 A. There towards the end she wasn't coping with
21 my brother's death. She was taking too much
22 medicine.

23 Q. How did you notice that?

24 A. She would fall asleep in the chair and she
25 wouldn't go to bed and get any rest, and she would

1 drop the glass of milk that she was trying to drink
2 and fall asleep and be real groggy.

3 Q. Did you come to the conclusion that there
4 was something wrong with her that you didn't
5 understand?

6 A. Yes.

7 Q. What did you do about it?

8 A. I went to -- she went into the hospital
9 after my brother's death and was having severe chest
10 pain, and it scared me enough to ask some questions
11 to the director of nursing how -- if she had been
12 okay, and the director of nursing said that --

13 THE COURT: Don't go into what someone else
14 said.

15 Q. (BY MS. DESCHAMPS-BRALY) Was your mother
16 taking prescription drugs?

17 A. Yes, she was.

18 Q. Do you know what kind of drugs she was
19 taking?

20 A. Valium and Elavil.

21 Q. Do you know what Elavil is for?

22 A. Her nerves.

23 Q. Do you know what the Valium is for?

24 A. Nerves.

25 Q. What hospital did she go into?

1 A. Valley Hope.

2 Q. What kind of institution is that?

3 A. It is a drug rehabilitation center.

4 Q. And was this after Sean's funeral?

5 A. Yes, it was.

6 Q. How long was she in there?

7 A. For a month.

8 Q. An has your mother been much better since?

9 A. Much.

10 Q. Now, before lunch we were talking about the
11 last time that Sean had to go into Valley View
12 Hospital. Would you tell us, why did you have to
13 take him in on that last occasion?

14 A. Because his fever was too high, and we
15 couldn't get his fever down, and he was miserable.

16 Q. Were you with him constantly in the hospital
17 that last time?

18 A. Yes, I was.

19 Q. Was he in pain?

20 A. Lots of pain.

21 Q. How do you know that, Marian, if he couldn't
22 talk to you?

23 A. He couldn't talk, but he would tell me with
24 his eyes what was wrong. I would question him, and
25 he would let me know what was wrong.

1 Q. What were your concerns about Sean during
2 that last time that he was in the hospital?

3 A. Like I said, his feeding tube wouldn't come
4 back -- go back down.

5 Q. Did you have any conversation with Sean
6 about his illness?

7 A. Yes, I did.

8 Q. What did you tell him?

9 A. I told him to go ahead and make his peace
10 with God, because we couldn't get the feeding tube
11 back down and there was a cancer tumor that was
12 causing it from not going back down. And my mother
13 called Doctor Glasgow to see if Doctor Glasgow would
14 put one in his stomach, and Doctor Glasgow finally
15 made my mother understand that that would be cruel to
16 keep feeding him.

17 Q. Did you take Sean home?

18 A. Yes, we did. He wanted to die at home.

19 Q. Was there something special that Sean was
20 trying to live for?

21 A. He was trying to see my brother's baby, and
22 he was just hanging on and hanging on, and my mother
23 kind of wanted to keep it quiet and not tell him that
24 he was dying, but I finally had to tell him to let go
25 because he was only making himself suffer. It

1 wouldn't be fair for him to see that baby and have to
2 leave.

3 Q. Were you with Sean on the morning that he
4 died?

5 A. Yes, I was. He was --

6 Q. Did you talk to Sean about letting you know
7 that he was going to die?

8 A. Yes.

9 Q. What had you asked him to do for you?

10 A. Before we took him home from the hospital,
11 said, "Sean, make your peace with God, and let me
12 know when you are going to pass away, because you are
13 going to know when you are going to die, and give me
14 the thumbs up so I will know."

15 Q. Could you please tell us what happened on
16 the morning of February 25th, 1984.

17 A. There was something wrong. He kept trying
18 to tell me something. I couldn't understand what he
19 was trying to tell me because I had forgotten that
20 when I told him in the hospital, and he kept giving
21 me the thumbs up, and I didn't understand what he was
22 saying.

23 I kept asking him, I went through
24 everything, everything, trying to ask him what was
25 wrong, and he just kept telling me. Finally he kept

1 telling me he was dying. I sat there on the couch,
2 and he started to change colors; and I called my
3 mother and she came in from the bedroom and she held
4 my brother in his last breath, and he died.

5 MS. DESCHAMPS-BRALY: Marian, I don't have
6 any further questions.

7 THE COURT: Cross-examine.

8 THE COURT: Would you like a
9 recess?

10 THE WITNESS: I'm fine.

11 THE COURT: Can you answer counsel's
12 questions?

13 THE WITNESS: Yes, I can.

14 CROSS-EXAMINATION

15 BY MR. FINNEGAN:

16 Q. Miss Marsee, do you feel up to answering a
17 few questions for me?

18 A. Yes, sir.

19 Q. I have just a very few that I would like to
20 ask you if you don't mind?

21 A. Okay.

22 Q. You have a twin sister, Melissa?

23 A. Yes, sir.

24 Q. In addition to your brother Sean, you have a
25 brother Jason and a brother Shannon?

1 A. Yes, sir.

2 Q. And Shannon is between Jason and Sean in
3 age?

4 A. Yes, sir.

5 Q. Now, did Shannon live at Talihina with Sean
6 during the year that Sean was living at Talihina?

7 A. Yes, he did.

8 Q. They were both going to school at Talihina?

9 A. Yes, sir.

10 Q. I believe you said that you are
11 three-and-a-half years older than Sean.

12 A. Yes, sir.

13 Q. Is that correct?

14 A. (Nodding yes).

15 Q. Did you say that you started smoking
16 cigarettes about the time he started using Red Man or
17 snuff?

18 A. I was smoking before he started.

19 Q. And at that time you were how old, 15?

20 A. 15 or 16. I can't remember.

21 Q. Now, did he start using Red Man Tobacco
22 before he started using snuff?

23 A. Yes, sir.

24 Q. And --

25 A. When we went fishing.

1 Q. Do you know how long he used chewing
2 tobacco?

3 A. Not very long at all. A couple of times I
4 seen him with it when we went fishing.

5 Q. I believe you told us in your deposition
6 that so far as you knew, Sean never tried to quit
7 using snuff or chewing tobacco, smokeless tobacco.

8 A. Just when the doctor told him to.

9 Q. After he was diagnosed?

10 A. Right.

11 Q. Do you remember where he placed the snuff?

12 A. Yes.

13 Q. Where did he place it?

14 A. On his right side.

15 Q. And where?

16 A. In his mouth (indicating), right here.

17 Q. Was it in the mouth or the corner of the
18 mouth or the lip or where? Can you remember?

19 A. It was more in his cheek.

20 Q. More in his cheek?

21 A. Uh-huh.

22 Q. Did you ever go to Doctor Hook with Sean?

23 A. No, sir.

24 MR. JENNINGS: I believe that's all. Thank
25 you very much.

1 THE COURT: Anything further?

2 MS. DESCHAMPS-BRALY: Nothing further, Your
3 Honor.

4 THE COURT: You may step down. Call your
5 next witness.

6 MS. DESCHAMPS-BRALY: Your Honor, at this
7 point we would move that all the medical records of
8 Sean Marsee since his birth be admitted into
9 evidence, and I believe that there is a stipulation
10 that there is no disagreement on counsel's part.

11 THE COURT: I thought we had those medical
12 records.

13 MR. JENNINGS: There is no objection, Your
14 Honor.

15 THE COURT: We don't?

16 MS. DESCHAMPS-BRALY: We have part of them,
17 but I would now ask that all of the medical records
18 since birth be admitted.

19 THE COURT: Where are they?

20 MS. DESCHAMPS-BRALY: We have them right
21 here.

22 THE COURT: Bring them up. We will need to
23 have them --

24 MS. DESCHAMPS-BRALY: Your Honor, we have
25 some other housekeeping matters that need taking care

1 of before we rest. We can wait until later if Your
2 Honor would prefer. We have no further witnesses.

3 THE COURT: All right. Why don't you come
4 up just a moment.

5 (The following proceedings were had AT THE SIDE
6 BAR.)

7 THE COURT: Are these the medical records?

8 MS. DESCHAMPS-BRALY: Yes, sir.

9 THE COURT: Okay. Those will be Plaintiff's
10 Exhibits --

11 MS. DESCHAMPS-BRALY: Can you read --

12 THE COURT: -- 66-A, 66-B, 66-C and 66-D,
13 and they will all be admitted without objection.

14 What else?

15 MR. BRALY: We are not exactly sure of the
16 status on the admission of the exhibits from Chairman
17 Bantles' deposition.

18 THE COURT: There are several exhibits from
19 that deposition which we have not gone over. What I
20 would like to do is go ahead and give you an
21 opportunity, if no one has any objection to this, to
22 go through and make sure that we have -- you can
23 compare what you have with her record and see if we
24 have omitted anything that you intend to offer.

25 MS. DESCHAMPS-BRALY: Could we have a short

1 break to have that done.

2 MR. BRALY: Do it overnight or take it up
3 the first thing in the morning.

4 THE COURT: Any problem with that?

5 MR. JENNINGS: No, Your Honor.

6 THE COURT: All I know of are the exhibits
7 during the Bantle deposition. I don't think you ever
8 formally moved those into evidence.

9 MR. BRALY: Well, some of them we did at a
10 bench conference.

11 THE COURT: I think that's right.

12 MR. BRALY: That's what I wanted to
13 clear up.

14 THE COURT: There is still the NIH exhibit
15 we need to deal with, maybe one or two others, but we
16 can deal with those later. Anything else?

17 MR. BRALY: No, I don't think so, Your
18 Honor.

19 THE COURT: So plaintiff rests?

20 MR. BRALY: Yes.

21 THE COURT: Do you wish to make a record?

22 MR. JENNINGS: No, I believe not, Your
23 Honor.

24 THE COURT: All right. Thank you.

25 MR. JENNINGS: We would reserve the right to

1 make a record at the conclusion of all of the
2 testimony.

3 THE COURT: Are you ready to proceed?

4 MR. JENNINGS: Yes, Your Honor.

5 THE COURT: Do you need a recess or
6 anything?

7 MR. JENNINGS: No, we are ready.

8 (The following proceedings were had IN OPEN
9 COURT.)

10 THE COURT: Ladies and gentlemen, the
11 plaintiffs have now rested their case and, defendant,
12 you may call your first witness.

13 KENNETH D. MACRAE, PH.D.,
14 called as a witness on behalf of the defendant, being
15 first duly sworn, testified as follows:

16 DIRECT EXAMINATION

17 BY MR. JENNINGS:

18 Q. If you will, pull that microphone around so
19 you can speak into it, please, sir. What is your
20 name?

21 A. I'm Kenneth Duncan Macrae.

22 Q. Where do you live?

23 A. I live in [DELETED]

24 Q. What is your business or profession?

25 A. I'm a medical statistician.

1 Q. Doctor Macrae, are you English?

2 A. No, I'm Scottish.

3 Q. How long have you lived in [DELETED]

4 A. Eleven years.

5 Q. Where did you receive your education?

6 A. I'm -- I went to school in Scotland and I
7 went to the university also in Scotland, in Aberdeen,
8 Aberdeen University.

9 Q. Did you get a degree from that university?

10 A. Yes, I got my MA and my Ph.D. from Aberdeen.

11 Q. In what year did you get your MA?

12 A. 1961.

13 Q. And your Ph.D.?

14 A. 1970.

15 Q. And what's your thesis in your Ph.D.?

16 A. On statistical decision-making.

17 Q. After you got your Ph.D., then what did you
18 do?

19 A. I became a lecturer in medical statistics at
20 the University in Belfast where I was until 1976.
21 Then I moved to the University of London to one of
22 the medical schools there, Charing Cross and
23 Westminster Medical School.

24 Q. Have you been there since?

25 A. I have been there since, yes.

1 Q. And are you teaching at the present time?

2 A. Yes, I am, yes.

3 Q. What subject are you teaching?

4 A. I teach medical statistics.

5 Q. Tell us what medical statistics involve.

6 A. It involves two main subjects. One is
7 clinical trials, which is testing treatments, drugs
8 and surgical treatments for their effectiveness, and
9 it involves epidemiology, which is investigating
10 Parkinson disease by statistical methods.

11 Q. Have you been personally involved in
12 epidemiological studies?

13 A. Yes, I have, yes.

14 Q. What role does the medical statistician play
15 in an epidemiological study?

16 A. He -- he's got a fundamental role in
17 designing the study to, as much as possible, make the
18 study as free from bias and confounding as
19 epidemiology ever can be. And he also has a
20 technical role in analyzing the results, because they
21 are the methods used to analyze epidemiological
22 studies required in technical statistical expertise.

23 Q. We have heard the terms "statistical
24 significance" used in this courtroom. Would you tell
25 the jury what that means?

1 A. Well, it doesn't mean what the word
2 "significant" normally means in the English language,
3 which is important. It -- the best synonym for
4 "significantly" is improbable or unlikely. It means,
5 in effect, that the difference or the association
6 found is unlikely to have occurred by chance alone,
7 but, of course, why it has occurred is another
8 question.

9 Q. Well, if it is not statistically
10 significant, it means it could have occurred by
11 chance alone; is that correct?

12 A. That's -- that's right, yes.

13 Q. And why it occurred is not explained, it
14 just could have occurred by chance and you don't know
15 why it occurs; is that correct?

16 A. Exactly, yes.

17 Q. All right. Now, you have personally been
18 involved in epidemiological studies, have you not?

19 A. Yes, I have, yes.

20 Q. Tell us what the purpose of an
21 epidemiological study is.

22 A. It's to -- really, the simplest is to
23 investigate associations between some exposure or
24 habit or lifestyle and some health outcome which
25 could be good or bad.

1 Q. And are there any limitations on
2 epidemiological studies, what you can establish by
3 them?

4 A. Yes. The fundamental point of
5 epidemiological studies is that they have to observe
6 human beings the way they are. They can't control
7 what human beings do or experiment on them. So we --
8 we have what is called observational research.

9 There can be many different explanations for
10 any association or difference between two groups that
11 we compare, and it may or may not be the difference
12 that we are interested in examining. That's our
13 basic research hypothesis.

14 So I think the basic problem with
15 epidemiology is that it is basic observation rather
16 than experiment.

17 Q. Are there any problems or limitations that
18 are built into an epidemiological study?

19 A. Yes. I mean fundamentally you have problems
20 of bias and confounding which will always make it
21 doubtful, except in very exceptional circumstances.
22 If any long-chance effect is actually a simple cause
23 and effect relationship, so that it is difficult to
24 draw simple conclusions from a epidemiological study
25 in the way that you can from a true experiment.

1 Q. And can you prove a causal connection or
2 causal relationship through an epidemiological study?

3 A. That, of course, is controversial, and it's
4 a highly debatable matter, in that there are
5 so-called criteria that some epidemiologists think
6 under certain circumstances establish causation. The
7 problem is that these criteria are ill-defined and
8 very open to biased interpretation. I think my
9 general view is that epidemiology alone can merely at
10 its best demonstrate associations. And that
11 causation is really not within the realm of
12 epidemiology.

13 Q. Doctor Macrae, are you familiar with a paper
14 known as the Winn Study?

15 A. I am, yes.

16 Q. What was that statement?

17 A. That was a retrospective case-control
18 comparison, comparing women in the Southeastern
19 United States, North Carolina, I think, who had a
20 diagnosis of cancer in one of several -- any one of
21 several sites in the general area of the mouth and
22 comparing these cases with a larger group of
23 individuals from the same part of the world, also
24 women, who did not have that particular diagnosis.

25 Q. And those women with whom the cases were

1 compared are called controls; is that correct?

2 A. They are called controls, yes.

3 Q. Do you know when that study was published?

4 A. The study was published, I think, in the New
5 England Journal of Medicine in 1981, I think the date
6 that comes to mind.

7 MR. JENNINGS: If the Court please, I
8 believe that that paper is in evidence as Plaintiff's
9 Exhibit 80 -- some letter.

10 MR. FINNEGAN: 80-L.

11 MR. JENNINGS: May I approach the witness,
12 Your Honor?

13 THE COURT: (Nodding yes).

14 (Handed to the witness).

15 THE WITNESS: Thank you.

16 Q. (BY MR. JENNINGS) Doctor Macrae, I have
17 just handed you what has been introduced in evidence
18 and marked as Plaintiff's Exhibit 80-L. Do you
19 recognize that paper?

20 A. Yes, I do, yes.

21 Q. And that is the Winn Study that was
22 published in the New England Journal of Medicine on
23 March 26, 1981; is that correct?

24 A. That's correct.

25 Q. Now, in addition to publishing this study in

1 the New England Journal of Medicine, did Doctor Winn
2 write her Ph.D. thesis on this subject?

3 A. Yes, she did, yes.

4 Q. And does the Ph.D. thesis expand upon what's
5 in this article?

6 A. Oh, very much so. The Ph.D. thesis is many,
7 many pages, several hundred. This is a short
8 article.

9 Q. And Doctor Winn made this study for the
10 purpose of satisfying the requirement of the Ph.D.
11 thesis; is that correct?

12 A. That's correct, yes, sir.

13 Q. You have, of course, read the exhibit that
14 is Plaintiff's Exhibit 80-L.

15 A. Yes.

16 Q. New England Journal of Medicine. Have you
17 read Doctor Winn's thesis?

18 A. Yes, I have.

19 Q. Have you at our request analyzed the paper
20 and the thesis?

21 A. Yes, I have.

22 Q. Tell the jury some of the details of Doctor
23 Winn's study.

24 A. Well, she first of all had to find her
25 cases, and she found her cases in two ways. She

1 examined death certificates and found individuals who
2 had died with the diagnosis of cancer in one of the
3 specified mouth sites.

4 Q. Doctor, how does she find that diagnosis?
5 How does she know what diagnosis was made?

6 A. Well, the diagnosis -- I haven't seen a
7 North Carolina death certificate, but diagnosis is
8 usually recorded on the death certificate, sometimes
9 in a numerical form, which is called an ICD. It is
10 an international classification of diseases. And
11 each disease has got a number, and cancers in the
12 mouth are called various numbers.

13 Q. That is coded by numbers?

14 A. Coded by numbers.

15 Q. All right, sir. All right. So she got some
16 of her cases from death certificates; is that
17 correct?

18 A. She did.

19 Q. And then did she get others from another
20 source?

21 A. Yes, she got others from patients who were
22 attending hospital. She had a number of those who
23 agreed to provide information, and she got other
24 patients, the so-called hospital cases, from patients
25 who were attending hospitals during the study period.

1 Q. Was that during the specified period of time
2 that she covered?

3 A. Yes. It was broadly a three-year period
4 between 1976, '77, '78, I think. It was that sort of
5 basic time period. It is slightly complicated, in
6 that the death certificate cases -- we have got them
7 here -- were from January, '76, to August, '78,
8 whereas the hospital cases were September, '75, to
9 August, '78. So the time periods weren't exactly the
10 same.

11 Q. And was there an effort to get every case of
12 oral cancer from those two sources during those
13 periods?

14 A. Yes, in women, of course.

15 Q. Just in women?

16 A. Just in women.

17 Q. Limit it to women?

18 A. Yes.

19 Q. Do you know how many cases she came up with
20 from that survey?

21 A. Yes. Initially she came up with I think it
22 is almost 300. I forget the precise number. I think
23 it might be 290 such cases. She got approaching 300
24 cases.

25 Q. And then did she cut that list down for any

1 reason?

2 A. Yes. Some of them she eliminated
3 immediately because they lived in parts of the state
4 which were inconvenient for interviewing. They lived
5 in remote areas, and she didn't feel the effort in
6 interviewing them was justified. And I think she
7 lost roughly 30 cases for this reason.

8 Q. Then did she, after she had lost the cases
9 she just didn't bother to pick up, did she lose any
10 others?

11 A. Oh, yes. She lost some because they
12 refused, the relatives refused or the doctor
13 responsible for the patient refused to let her
14 interview them. That was a small number. She also
15 lost, strangely enough, four cases who turned out not
16 to have oral cancer of the type she was interested
17 in. There apparently had been some error in the
18 process of selecting the cases, and she lost four for
19 that reason.

20 Q. And how many cases did she finally wind up
21 with that she studied?

22 A. She actually analyzes in her paper 232
23 cases.

24 Q. Now, with regard to controls, how many
25 controls did she seek for those cases that she had?

1 A. She tried to get two controls for each case.
2 She didn't, of course, always get two controls for
3 each case.

4 Q. And, as I understand it, she was seeking
5 matched controls. What does that mean?

6 A. Well, she obviously, because her patients
7 are cases that were women, she wanted female
8 controls. Secondly, many habits, habits of
9 lifestyle, vary where you live, when you live in the
10 town, in the country, or in a big city, and so she
11 matched the cases for area of residence and indeed
12 for race. She had white patients, white cases, she
13 had black cases, and I think she had some American
14 Indians, so she tried to match for race as well.

15 And finally, most important, she wanted
16 cases on controls to be very similar in terms of
17 age. She didn't want, say, old cases to be compared
18 with younger controls.

19 Q. Now, when you speak of matched controls, you
20 are speaking of a control selected to go with a
21 certain case; is that right?

22 A. Exactly, yes.

23 Q. Instead of having, say, 232 cases, now we go
24 out and we get 464 controls, we will have two for
25 each one, it wasn't like that. It was you actually

1 were matching, trying to match two controls to each
2 case?

3 A. Exactly, yes.

4 Q. All right, sir. Now, you spoke of
5 interviewing. Tell us about that.

6 A. Well, she wanted to find out information
7 about various things that have been hypothesized,
8 suspected as being relevant to the issue which is
9 what might be associated with cancer of various sites
10 in the mouth.

11 So she had a very extensive questionnaire
12 covering many pages, I think eight pages of
13 questions, which she asked them about diet,
14 occupation, alcohol, smoking, or smokeless tobacco.
15 Many aspects of the patient's life were asked about
16 in this questionnaire.

17 Of course, the problem immediately arises
18 can you actually interview the cases in the
19 controls. Very obviously many of her cases have been
20 obtained from a death certificate sample. The cases
21 were already dead by the time she started to do the
22 study, so with all of these she had to get the
23 information from relatives of the patients, not from
24 the patients.

25 Q. Now, were the death cases matched with

1 deceased controls?

2 A. They were, yes.

3 Q. In all of those cases the information would
4 come not from the patient but from a relative?

5 A. From a relative, yes.

6 Q. Or maybe from a doctor or a friend or from
7 some other source?

8 A. In fact, it was a relative. I don't think
9 doctors or friends entered into it.

10 Q. All right. Now, how about the hospital
11 cases? Was she able to interview the case and the
12 control in each of the hospital cases?

13 A. No. In fact, she strangely enough wasn't.
14 It wasn't strangely enough actually, because some of
15 the hospital cases died before she could interview
16 them. I think 42 of the hospital cases were also on
17 the death certificate sample. And some of them they
18 were too old or too ill to be interviewed
19 personally. In fact, of the 232 cases that she had
20 data from, I think the number is 69 what she actually
21 interviewed personally. The vast majority of her
22 cases, three-quarters, the data came from a relative,
23 not from the patient herself.

24 Q. How about the controls?

25 A. The controls, more of the hospital controls

1 were interviewed personally. In fact, I think the
2 figure is -- I can check on the precise number later,
3 but the figure is that something like 27 percent of
4 cases were interviewed personally, just over a
5 quarter, but nearly half of the controls were. It
6 was about 47 percent of the controls were interviewed
7 personally.

8 Q. What, if any, problem is there with regard
9 to the study where the case or the control is not
10 personally interviewed but you get information from
11 relatives?

12 A. Well, one is obviously knowledge. Does the
13 person have the information? Some information is in
14 fact extremely difficult, even for the subject
15 themselves to answer. If you ask somebody "how much
16 butter do you eat in a week," it is very difficult to
17 give an answer to that. Even I could probably find
18 that difficult to answer. So many of her questions
19 were of that sort, or some are obviously less
20 difficult in terms of the question.

21 The other is with a retrospective study you
22 are asking data of people, of the relatives, who have
23 perhaps died or have been treated for a rather
24 unpleasant and serious condition. And their answers
25 may well be affected by the fact that they have had a

1 mouth cancer. This effect would -- I mean this is
2 plausible, of course. We don't know, that is the
3 nature of epidemiology, but it is possible there
4 might be a difference in the way that the cases or
5 the relatives saw the questions and the way that the
6 controls saw the questions who perhaps had an illness
7 not at all related to the mouth in any way.

8 So that with retrospective data, where you
9 try to collect the data after the event, the person
10 that is providing the data can be affected by the
11 circumstances. What's also the case is that the
12 person asking the questions also will know which is a
13 case and which is a control. You can't conceal that
14 from the people asking the questions.

15 Q. Is reliability of information always a
16 problem in an epidemiological study?

17 A. To a greater or lesser extent,
18 reliability -- accuracy is always a problem with
19 retrospective data and, indeed, reporting bias,
20 reporting enthusiasm is also a problem.

21 Q. Doctor Macrae, before we go any further, as
22 epidemiological studies go, how do you evaluate the
23 Winn Study?

24 A. I think it is a much better than average
25 case control study.

1 Q. You say a case control study. Is there some
2 other kind of epidemiological study?

3 A. Yes. The main other, what is called,
4 analytical study is called a prospective, a cohort
5 study, and this study has a completely different
6 logic that used -- you compare those who are exposed
7 to some habit or substance with those who are not,
8 and you see what effects the various comments, what
9 sequences ensue, and you follow them through time so
10 you have recorded the data on exposure, the use of
11 various substances, before the patient becomes ill.

12 So in the prospective study the data can't
13 be contaminated or biased by what later happens. It
14 is still observational, so it is still open to
15 problems of interpretation, but this is why a
16 prospective study is less susceptible to information
17 bias, whereas the retrospective case study is
18 inevitably suspect in that regard.

19 Q. Is there any problem with doing a cohort or
20 prospective study as far as oral cancer is concerned?

21 A. Oh, yes, an enormous problem. Because if a
22 condition is rare and it takes many years to develop,
23 Winn's patients, Winn's cases, the vast majority of
24 them were in their sixties, seventies or eighties.
25 There are very few patients under the age of sixty or

1 fifty in that study.

2 Now, if you are -- many of them began
3 snuff-dipping or whatever else they did, smoking,
4 drinking, eating highly spiced foods, working at a
5 very early age. Obviously you would need a huge
6 population followed virtually from birth into their
7 eighties to do a prospective study. As a person who
8 does statistical research, if you are studying a
9 creature whose life span is longer than your own,
10 i.e., a male statistician studying women, you are
11 going to be dead yourself before you get to the data,
12 so you can't in practice do cohort studies with any
13 great ease in this particular condition.

14 Q. All right, sir. Let me ask you another
15 question about the Winn Study. From your analysis of
16 the Winn Study, does that study support an opinion in
17 any way that tongue cancer is caused by dipping
18 snuff?

19 A. No. Of course, it doesn't just not support
20 it. It denies the fact that there is an association,
21 because it shows no statistical association
22 whatsoever with tongue cancer.

23 Q. Doctor McCrae, you spoke of the age of the
24 cases in the Winn Study. Was the Winn Study
25 essentially a study of old people?

1 A. Largely, yes, yes.

2 Q. But it was a study of all of the oral cancer
3 cases in the particular defined population?

4 A. That's correct, yes.

5 Q. And it turned out that all of them were old
6 people, or not all but most of them?

7 A. The vast majority. I think one patient was
8 in her twenties and a few more were in their
9 thirties, but the vast majority were over the age of
10 60.

11 MR. JENNINGS: Excuse me just a moment.

12 If the Court please, we are using this for
13 our demonstration purposes. We are not offering it
14 as an exhibit. It has been marked for identification
15 as Defendant's Exhibit 6.

16 Q. (BY MR. JENNINGS) Doctor McCrae, that
17 exhibit was prepared by us from information that you
18 gave us. Does it correctly reflect the number of
19 cases in the Winn Study under the age of 30?

20 A. It does, yes.

21 Q. And how many were there?

22 A. One.

23 Q. And that was age 20?

24 A. That's correct, yes.

25 Q. And there was a control for that case, also

1 age 20?

2 A. Yes. She only managed to get one control
3 for that case, not the two that she attempted to get.

4 Q. And as in the entire study, the case had
5 oral cancer and the control did not.

6 A. That's correct, yes.

7 Q. None of the controls had oral cancer.

8 A. No, none.

9 Q. All of the cases had oral cancer?

10 A. That's right.

11 Q. And in that case of the 20-year-old, which
12 was one out of 232, the case did not use snuff and
13 did not use chewing tobacco; is that correct?

14 A. Yes, that's correct, yes.

15 Q. I see. Now, Doctor Macrae, in addition to
16 the study of the paper itself and a review of the
17 Winn thesis, have you examined the underlying data
18 that formed the basis of the Winn Study?

19 A. On a certain level I have. I analyzed the
20 data as it was put onto the computer. What I haven't
21 done is verified that what was put onto the computer
22 corresponded to any paper records or that the paper
23 records corresponded to what was true about the
24 patients.

25 Q. Have you correlated what was on the computer

1 with what was in the thesis and in the paper
2 sufficiently to satisfy yourself that the data that
3 you were looking at was in fact the data that Doctor
4 Winn was relying upon?

5 A. Yes. All the figures which were in the
6 paper, in the thesis, tallied with what I could
7 independently obtain from the computer tapes supplied
8 from Doctor Winn.

9 Q. From that underlying data did you determine
10 how many of the 232 cases had tongue cancer?

11 A. Yes, yes, I did. The number was 50.

12 Q. There were 50?

13 A. There were 50, yes.

14 Q. Do you know how many of those were hospital
15 cases and how many were death cases?

16 A. I think 36 were hospital cases and 14 were
17 death cases.

18 Q. And did you determine the information
19 specifically about each of those cases with regard to
20 use of tobacco, age, so forth?

21 A. Yes, I did, yes.

22 Q. Doctor McCrae, again, are these charts that
23 were prepared by us from information furnished to us
24 by you?

25 A. Yes, they are, yes.

1 Q. Have you examined them to see if they are
2 accurate from the information that was contained in
3 Doctor Winn's underlying data?

4 A. Yes, I checked them this morning.

5 MR. BRALY: If it please the court, could we
6 have copies of these?

7 MR. JENNINGS: Sure.

8 MR. BRALY: We have never seen them before.

9 MR. JENNINGS: Here they are.

10 (Handed to counsel).

11 MR. BRALY: May we approach the bench on
12 this matter?

13 (The following proceedings were had AT THE SIDE
14 BAR.)

15 MR. BRALY: Counsel, have these been
16 previously furnished?

17 MR. JENNINGS: The data has been furnished.

18 MR. BRALY: Have the charts been previously
19 furnished?

20 MR. JENNINGS: No, the charts have not been
21 furnished.

22 MR. BRALY: We will object, Your Honor.

23 MR. JENNINGS: If the Court please, he had
24 his own witness write up this same sort of thing and
25 typed during the course of this testimony. All we

1 have done is prepare it ahead of time.

2 THE COURT: Do you intend to offer it as an
3 exhibit?

4 MR. JENNINGS: No, we are not. If you
5 recall, --

6 MR. BRALY: We asked for the data on this
7 timetable, Mr. Jennings, two or three weeks ago
8 during the course of the trial. He said he would
9 furnish that at trial. If he did, it was furnished
10 in the form of a magnetic tape, but they could easily
11 have furnished those charts. They have obviously had
12 them for some time and they go to the heart of an
13 important study. We think that it is unfair
14 surprise.

15 MS. DESCHAMPS-BRALY: We have no way of
16 transcribing that magnetic tape.

17 MR. JENNINGS: If the Court please, this is
18 work product. We furnished them the data from which
19 they could have prepared the charts. They have got
20 the data.

21 MR. BRALY: This Court gave strict
22 instructions about trial exhibits being furnished.

23 MR. JENNINGS: These are not exhibits.

24 MR. BRALY: And the Court has very
25 strict --

1 THE COURT: I understand your objection.
2 What is the difference between if he is not offering
3 it as an exhibit, between using this as a
4 demonstrative exhibit or having him write the same
5 stuff in a report. I don't see that there is any
6 difference between what you did with exhibits which
7 you didn't offer and just had him write them up
8 there.

9 MR. BRALY: Well, for instance, Doctor
10 Horrell, the data that he was presenting was the
11 company's own data, and it was in their annual
12 reports.

13 THE COURT: I will overrule the objection.

14 MR. BRALY: And the annual reports haven't
15 been admitted into evidence.

16 THE COURT: I will overrule the objection.

17 MR. BRALY: Okay.

18 (The following proceedings were had IN OPEN
19 COURT.)

20 MR. JENNINGS: If the Court please, may I
21 question the witness from here?

22 THE COURT: Yes.

23 MR. JENNINGS: And I will try to keep my
24 voice up.

25 Q. (BY MR. JENNINGS) Tell me, Doctor McCrae,

1 the chart there that is entitled "Hospital Series -
2 Tongue Cancer Cases," what does that show?

3 A. Well, it -- it lists the 36 cases with their
4 matched controls, whether there are one or two. Or,
5 as you can see, there are two cases there that
6 actually don't have any controls, so I numbered them,
7 or at least they have been numbered 1 to 36, and the
8 ID is the reference number that Doctor Winn used on
9 the computer file to refer to the case on the two
10 controls. That's Doctor Winn's identity number.

11 Now, in the snuff use a zero means that
12 they, the case control, did not use snuff. It was
13 not a snuff dipper.

14 Q. According to the information on the tape?

15 A. According to Doctor Winn's computer tape.

16 Q. Right?

17 A. A one means that the case under control did,
18 so you can see the pattern of zeros and ones and
19 sometimes a case uses snuff and the control doesn't,
20 or it's the other way around. But in total, all of
21 these 36 cases, you see that 14 of them have a one
22 next to them, so 14 were snuff dippers, and obviously
23 it follows that 22 were not.

24 Q. How about the controls?

25 A. Well, the controls. The controls are more

1 complicated, because she didn't always get a control
2 and she often didn't get two controls. So she
3 actually manages to get controls in fact for 33 of
4 these 36 cases. On all the 33 controls, 11 were
5 dippers and 22 were not, a very similar proportion to
6 the 36 cases.

7 Now, she didn't manage to get data on a
8 second control for 13 of these 36, so 13 of the cases
9 don't have two controls. Five out of these 20, three
10 that she did get second controls for, five of them
11 were dippers, obviously, 18 were not.

12 So you can see that in this particular
13 tabulation that the proportion of snuff dippers in
14 tongue cancer cases is, first of all, a minority.
15 Fewer than half the tongue cancer cases were snuff
16 dippers at all. And the proportion is very similar
17 in the cases in the controls, suggesting really there
18 is no difference in snuff usage in tongue cancer
19 cases.

20 Q. All right. Now, in addition to showing
21 snuff use, you also show smoking; is that correct?

22 A. That's -- that's correct. Smoking, although
23 it is not totaled up there, one can total them up, a
24 zero and one means the same. Zero means nonsmoke,
25 one means a smoker, and it tabulates the cases on

1 controls. And, in fact, if you add them up, which I
2 will quickly do, one, two, three, four, five, six,
3 seven, eight, nine, ten, eleven, twelve, yes, I think
4 it's twelve, I can check that basically, but it's
5 there. 12 of the cases, one, two, three, four, five,
6 six, seven, eight, nine, ten, eleven, I think it is
7 12 and 11. It is very approximately equal anyway.
8 So the cases on the controls are very similar both in
9 snuff-dipping and in smoking habits.

10 Q. Now, in order to understand the complete
11 chart, let's take the number 1 with the ID 127, --

12 A. Yes.

13 Q. -- and we go across under snuff use and we
14 show the case did not use snuff.

15 A. That's correct.

16 Q. Or I assume that is any smokeless tobacco.

17 A. No, that's --

18 Q. These people were all involved -- she was
19 studying snuff-dipping; is that correct?

20 A. She was studying snuff dipping.

21 Q. Okay. So neither Control 1 or 2 used snuff;
22 is that right?

23 A. That's correct.

24 Q. The smoking under the smoking column, the
25 case did not smoke, Control 1 did not smoke,

1 Control 2 did smoke?

2 A. That's exactly right, yes.

3 Q. So out of that particular case, the case and
4 control matched, you had one snuff dipper who was a
5 control and who did not have cancer.

6 A. No, one smoker, not snuff dipper.

7 Q. Excuse me?

8 A. Yes.

9 Q. One smoker who did not have cancer and was a
10 control, and you had one case that did not use either
11 snuff or smoked and had cancer?

12 A. No, that case of no tobacco usage of either
13 sort.

14 Q. Pardon?

15 A. That case of no tobacco use of either sort.

16 Q. That's what I say. They neither used snuff
17 nor smoked, that had cancer?

18 A. That's correct.

19 Q. And then you have age there. You show the
20 age of the case and the age of each control, and they
21 were all the same age.

22 A. Yes.

23 Q. And then you show the age began snuff.

24 Well, none of them ever used snuff. And years used
25 snuff, there were none?

1 A. Yes, sir.

2 Q. Now, you show the same information across
3 the lines for the other 35 cases; is that correct?

4 A. Yes.

5 Q. Now, let's look at No. 4 with the ID 140.

6 A. Yes.

7 Q. That shows a snuff user for the case. No
8 snuff use of either control, no smoking with either
9 cases or controls. 74 years old for the case, 74 and
10 75 for the control. The cases using snuff for 12
11 years -- no, excuse me, began snuff 12 years --

12 A. Age 12 years.

13 Q. At age 12? Excuse me.

14 A. Yes.

15 Q. And it used snuff for two years?

16 A. Yes. That's a curious thing. You see how
17 short the snuff usage was on this patient who began
18 using snuff at the age of 12. She used it for a
19 total of two years and entered the study at the age
20 of 74.

21 Q. So out of the 62 years between age 12 and
22 age 74, the case had used snuff two of those years,
23 according to that?

24 A. Two of those years, yes.

25 Q. According to the information?

1 A. That's what the computer file states, yes.

2 Q. All right. Now, Doctor Macrae, using
3 statistical methods and making a study of those
4 figures, did you come up with a figure as to the
5 relative risk of having oral cancer in one who used
6 snuff?

7 A. Yes. The figure is just greater than one.
8 It is 1.11, 1.2. I have got the exact figure, which
9 I can give you, in my notes. But it is almost one,
10 and, of course, there is no suggestion that it's
11 different from one by any large amount and, in fact,
12 when you put 14 out of 36, there's 11 out of 33, a
13 difference of three. Of course, the denominator is
14 different as well, could easily be a chance
15 difference. We are talking about a tiny difference.

16 Q. If I am interpreting right, if you had three
17 more controls, No. 1, so that that brought it up to
18 the 36 with the cases and all three of those happened
19 to use snuff, then you would have an exact equality?

20 A. It wouldn't even have to be that, because
21 you have fewer controls. What, it is an easier
22 calculation if you trim out the three cases without
23 controls, that makes it 12 out of 33 for the cases,
24 because you see if I take you through this, I hope
25 this is readable, that Case 7 does not have any

1 controls, ID 156. That's a dipper. So you would
2 reduce the number of cases to make them comparable to
3 the controls from 36 to 35 and reduce the number of
4 dipper from 14 to 13.

5 And you do the same with Case 20, who is a
6 dipper but has no controls, so that brings it down to
7 12 in 34. On Case 29 it is a nondipper, but there is
8 no controls, so it is 12 out of 33, as opposed to 11
9 out of 33. So the extra number of dippers in these
10 cases when you take cases who have controls is one.

11 Q. Well, what is the rationale or reason for
12 taking out the cases that don't have a control?

13 A. Well, they obviously, if you take No. 29, an
14 extreme case, that was a nondipper who was very
15 young. This person was age 33. In fact, it was one
16 of the two youngest tongue cancer cases in the study.
17 There is another 33-year-old somewhere else in the
18 data, who I think is that -- no, I think it should be
19 in this one. I think there were two 33-year-olds
20 somewhere. I can't quite find it in running my eye
21 down it at the moment, but this 33-year-old had no
22 case -- no controls, so as most of the other cases
23 and controls are much older, it would be, I think, a
24 very biased comparison to compare a 33-year-old case
25 with controls. The majority of them when you look at

1 this are age 50, 60, 70, much, much older.. So I
2 think you have to take out the cases who don't have
3 controls when you compare the cases and controls.

4 Q. But even if you don't take out the cases
5 without controls, you do not get a relative risk that
6 you consider significant; is that correct?

7 A. You don't have relative risk, no.

8 Q. All right, sir. Incidentally, how many
9 cases in the hospital series did not use tobacco in
10 any form?

11 A. I have that figure somewhere. I think it is
12 about a third of them approximately. I can count it
13 up. I have them in my notes, if you wish to look at
14 them.

15 Q. I wish you would look at them, I think it is
16 a third of them. I think it is 12 out of 36, but --

17 A. One, two, three, four, five, six, seven,
18 eight, nine, ten, eleven, twelve, yes, I get 12.
19 There is 12 out of 36.

20 Q. So 12 of the 36 cases with tongue cancer did
21 not use tobacco, according to the information that
22 was --

23 A. Exactly right.

24 Q. Now, Doctor Macrae, if you would, look at
25 the death certificate studies, and that shows the

1 same information with regard to the death certificate
2 cases; is that correct?

3 A. That's right, yes.

4 Q. And there were 14 of those.

5 A. That's right.

6 Q. So that made a total of hospital and death
7 certificates of 50?

8 A. Of 50, yes.

9 Q. All right, sir. And how did you come out on
10 the analysis of the relationship or relative risk
11 between use of snuff and oral cancer with the
12 hospital cases?

13 A. Well, in fact, that, if you just look at the
14 first control, would be exactly equal, because the
15 last of the 14 cases is a dipper, but that case
16 doesn't have any controls. So although the total
17 number of dippers is six of the 14, it, to make it
18 comparable, it should be five out of 30. You lose a
19 dipper and you lose a case.

20 Now, if you take, in fact, the second
21 control, in fact, the proportion of dippers in the
22 second control is higher. You have six dippers and
23 only 11 controls, so in this case, in the death
24 certificate cases, if you calculate relative risk, it
25 is actually less than one. In fact, the precise

1 figure, if I remember, I think it is .74, which is
2 consistent but, of course, as epidemiology can prove
3 very little, if anything, it is consistent with the
4 hypothesis that snuff protects against fatal tongue
5 cancer. And that's what the figure shows.

6 Q. If you just relied on those figures, that --

7 A. Yes.

8 Q. -- was a possible conclusion?

9 A. If you take the numbers at face value, it is
10 consistent with a protective effect of snuff as
11 against fatal tongue cancer.

12 Q. You don't reach that conclusion?

13 A. I don't believe that's true.

14 Q. All right, sir. But it is possible in this
15 type of analysis to get a relative risk of less than
16 one --

17 A. Oh, yes.

18 Q. -- by chance?

19 A. Of course. I mean we don't have many tongue
20 cancer cases. Are we talking about a difference of
21 one or two dippers? So it is -- one wouldn't make
22 anything substantive of that either way.

23 Q. All right. Now, in the death certificate
24 cases, how many of the cases of tongue cancer neither
25 smoked nor used snuff?

1 A. Let's see if I can count that. One, two,
2 three -- I think it is three from my count. Yes,
3 three, three is the number.

4 Q. So out of the 50 cases, the total of the 36
5 and 14, there were 15 of them who did not use
6 tobacco?

7 A. That's right, 15 --

8 Q. And they had cancer of the tongue?

9 A. They did indeed, yes.

10 MR. JENNINGS: May I move this, Your Honor,
11 so I can see?

12 THE COURT: Yes.

13 Q. (BY MR. JENNINGS) Doctor McCrae, did Doctor
14 Winn reach any conclusions with regard to the effect
15 of using both snuff and smoking in her overall study?

16 A. Well, I think the word "conclusion" is
17 putting it a bit strongly, but she found and said
18 that the risk or the association between
19 snuff-dipping and oral cancer in general was stronger
20 in nonsmokers than in smokers.

21 Now, what this is -- what this means is, of
22 course, the question. I mean it is consistent with
23 smoking protecting against any effect that snuff
24 might have or snuff protecting against any effect
25 that smoking might have but, of course, being

1 consistent with that hypothesis is one thing, but
2 proving is quite another.

3 Q. Well, did she find that snuff dippers who
4 also smoked, did she come up with a figure that there
5 was a lower relative risk if you also smoked?

6 A. Yes. The relative risk for snuff dippers
7 who smoked was lower than for snuff dippers who did
8 not smoke.

9 Q. Doctor McCrae, do you know whether or not
10 Doctor Winn herself reached any conclusions with
11 regard to whether or not snuff-dipping caused cancer
12 of the tongue?

13 A. She barely mentions cancer of the tongue as
14 a separate issue in either paper or her thesis.

15 Q. In her thesis did she set out specifically
16 what site she felt she did have an association with?

17 A. Yes. Being her main positive association is
18 in the gum and buccal region of the mouth.

19 Q. And when we speak of the gum and buccal
20 region, this is the gum all around here
21 (indicating), --

22 A. (Nodding yes).

23 Q. -- and the buccal would be the inside of the
24 cheek?

25 A. The cheek, if you place your finger between

1 your cheek and your gum.

2 MR. JENNINGS: This is identified as
3 Defendant's Exhibit 55.

4 THE COURT: Defendant's 55.

5 MR. JENNINGS: 55, yes, Your Honor.

6 Q. (BY MR. JENNINGS) Doctor McCrae, can you
7 see that?

8 A. Yes, I can, yes.

9 Q. You recognize what that is?

10 A. Yes, I do. That's Table 3 which was
11 published in our New England Journal of Medicine, an
12 article in 1981.

13 Q. That would be Doctor Winn's report that was
14 published?

15 A. That's a published table, yes.

16 Q. All right, sir. And --

17 THE COURT: Are you going to offer this as
18 an exhibit.

19 MR. JENNINGS: I am not introducing it, Your
20 Honor.

21 THE COURT: It is already in evidence.

22 MR. JENNINGS: It is a table from the paper
23 that is already in evidence.

24 THE COURT: All right.

25 Q. (BY MR. JENNINGS) Now, from those figures,

1 did Doctor Winn reach and express any conclusion
2 about relative risk?

3 A. Yes. The figure she obviously is most
4 impressed by there is the number 47.5 in the relative
5 risk column, and that has been widely quoted as being
6 the result of the Winn Study. That is a relative
7 risk that applies to women who have dipped snuff for
8 at least 50 years, at least 50 years.

9 And there are things to notice there, too,
10 that she restricted this analysis, where you see in
11 the final print at the top to nonsmokers and the
12 effect of this is to increase the figure because
13 smokers have a lower risk, and she also restricted
14 the risk to the hospital sample and she excluded the
15 death certificate cases and again the death
16 certificate cases of a lower risk.

17 In fact, the total number of cases shown for
18 gum and buccal mucosa there, if you add two, plus
19 three, plus ten, plus 15 in the cases column, adds up
20 to 30. In fact, in her study there were 50 patients
21 who had gum and buccal cancer, and so to get her
22 relative risk of 47.5, 20 of the 50, 40 percent of
23 the cases, were left out.

24 Q. And she also left out these 15?

25 A. Oh -- well, in fact, the technicality of

1 relative risk is that you compare the zero row, the
2 two in the 34, with each succeeding row. So what she
3 is really saying is that the comparison is zero with
4 50 gives you the number 47.5. So she is saying that
5 the rate of snuff usage in the cases and controls
6 would lead you, if the duration of usage was more
7 than 50 years, she would conclude that the relative
8 risk was 47.5. But to make that statement she has to
9 compare the 50-year-plus users with the zero year
10 users.

11 Q. I see. Well, now, that figure of 47.5 has
12 been very frequently quoted as fiftyfold, has it not?

13 A. Yes.

14 Q. It has been rounded up to 50 from 47.5, and
15 the 47.5 figure was arrived at by using the most
16 favorable comparison for the purpose of increasing
17 the relative risk; is that right?

18 A. Yes. That is -- when you look at all the
19 possible calculations you can do in the Winn Study,
20 that is the single highest relative risk you can find
21 in the study.

22 Q. And do you have an expression that you
23 describe that method by?

24 A. Yes. There is a saying that in statistics,
25 if you torture the data enough, it will eventually

1 confess, and this looks like, well, a possible
2 example of data torture.

3 Q. All right, sir. Now, Doctor Macrae, I want
4 to go back for a moment, if I can, to the tongue
5 cancer cases, and you have already pointed out that
6 there were few cases below -- did you say 60?

7 A. Under the age of 60 --

8 Q. Yes.

9 A. -- did you say? Yes, I looked at the
10 younger cases, and I took 60 as -- or less, or less
11 than 60 as my definition of young, because there are
12 so few young cases.

13 Q. All right, sir. And here on the death cases
14 you have one age 41?

15 A. And one quoted on age 57.

16 Q. And the next youngest was 57?

17 A. Yes.

18 Q. And everybody else is 60 or more?

19 A. That's correct.

20 Q. With two, four, six, seven out of the 14 or
21 half of them being 80 years old; is that right?

22 A. Yes, this is an elderly population..

23 Q. Now, under the hospital series, if you look
24 at ages, you see a 40-year-old, No. 15.

25 A. Yes, sir. If you take 60 as the dividing

1 line, you can start at the top, there are two
2 58-year-olds, with Cases 1 and 2. Neither of them
3 were snuff dippers. The next under 60 is No.
4 8, 57-year-old who is not a snuff dipper.

5 The next one is 12, 12 and 13 are both 53,
6 neither of them is a dipper; and 14 is a 50-year-old
7 who is not a dipper. This is No. 15, is one of the
8 two cases under the age of 60 who is a dipper, that
9 is the 40-year-old, Case 15, so that is the first
10 one.

11 If you go down and followed, you find the
12 second one, which is No. 25, that is the 46-year-old
13 who was a dipper. 27 is a 47-year-old, not a dipper.
14 29, and she doesn't have a control, but that is one
15 of the younger of the two cases -- one of the two
16 youngest cases, that is not a dipper, the
17 33-year-old, and the next 33-year-old is not No. 31,
18 who is also not a dipper, and that's it.

19 So you find in the whole study two patients
20 under the age of 60 with tongue cancer who are
21 dippers and 12 who are not.

22 Q. Have you run the same sort of analysis of
23 the death certificate cases?

24 A. Yes. None of -- none of the young -- by
25 young I mean under 60 -- none of the two young loss.

1 cases was a snuff dipper.

2 Q. I will accept that definition.

3 A. Thank you.

4 Q. Here is one 41, not a snuff dipper?

5 A. Snuff dipper, and then the second to last
6 one, No. 12 was -- she is not a snuff dipper either.

7 Q. Doctor McCrae, are you familiar with any
8 other epidemiological study that has been done in the
9 United States with regard to tongue cancers and the
10 use of smokeless tobacco?

11 A. Well, in general, the epidemiological
12 studies on oral cancer will usually contain some
13 tongue cases, but as with Doctor Winn, in the vast
14 majority of papers the tongue cases are not
15 identified separately. So, in fact, our information
16 about tongue cancer from the epidemiology is
17 virtually nil. And, in fact, it was only by getting
18 the computer tapes from Doctor Winn that we were able
19 to find out the evidence which I have just been
20 showing to you today.

21 Q. With regard to the age factor, did you also
22 analyze the data with regard to the buccal cavity and
23 the gum from an age point of view?

24 A. Yes, I did, as well.

25 Q. And what did that turn up?

1 A. Well, there were two patients under the age
2 of 60, under 50, 48 out of the 50 were, gum and
3 buccal cancer just does not occur virtually -- I mean
4 it's a disease of the elderly.

5 Q. Out of 2350 cases of the even buccal or
6 gum, --

7 A. Yes.

8 Q. -- only two were under 50?

9 A. Under 60.

10 Q. Under 60?

11 A. Under 60, yes.

12 Q. Under 60 years of age. Doctor McCrae, I
13 think for the jury's benefit you need to show them
14 how you go about calculating relative risk. Could
15 you do that?

16 A. Yes. Could I write on something?

17 Q. Pardon? Sure.

18 A. Could I --

19 Q. Go ahead.

20 A. You basically set the data up into a table
21 with four boxes. You list the cases here and you
22 list the controls there.

23 Q. You are going to have to keep your voice up,
24 because you don't have a microphone, Doctor.

25 A. Okay. Let me keep the numbers simple and

1 just assume that we have ten cases. We will keep it
2 really simple, and we will put ten controls, and
3 supposing we find out that, say, two of the cases
4 smoked, eight do not. Supposing one of the controls
5 smoked and nine do not.

6 Now, the relative risk is calculated in a
7 peculiar way. You have to do this by the
8 retrospective study. It is called an odds ratio, to
9 be technical it is the odd's ratio estimate of the
10 relative risk. And that's here because it's called a
11 cross-product. It is two times nine over one times
12 eight, which will be 18 over 8, which will be 2.25.

13 I don't want people to feel as if they were
14 back to school again. But it is quite a simple
15 calculation. At least that's the simplest way you
16 can do the calculation. There are more complicated
17 ways which Doctor Winn herself used. The complicated
18 ways are taking into account the matching of the
19 cases and the controls, and you effectively need a
20 computer to do that. But this gives a very good
21 estimate of what the more complicated methods do.
22 That's called the odds ratio estimate of relative
23 risk.

24 Q. And you say that different people might
25 compute the relative risk differently, but that's the

1 odds ratio for relative risk; is that correct?

2 A. Yes, that's the simplest method that is
3 valid to use in a case control study.

4 Q. Doctor McCrae, I don't want to get too
5 technical or too complicated, but how would you apply
6 the question of statistical significance to that
7 computation?

8 A. Well, the simple answer is that statistical
9 significance depends on the size of the relative risk
10 and on the number of cases on which it is based.
11 And, in fact, I think the jury would find Doctor
12 Winn's table a very valuable guide to this concept.
13 The very last column in that table is called an eight
14 percent confidence interval.

15 Now, that is quite a complicated calculation
16 to carry out, but basically what it does is it says
17 by chance how different from the number in the data
18 could the relative risk actually be. As we are
19 talking about the 47.5, the confidence interval for
20 that goes from 9.1 to 249.5. So random chance
21 variation could mean that instead of the risk being
22 47.5, it could actually be 9.1 or it could be
23 something greater than that or it could be as high as
24 249.5.

25 Now, the important thing to establish with

1 that is, that is looking purely at chance. If she
2 had ten times as many cases, it would make that
3 interval much narrower.

4 Now, a statistically significant risk or
5 relative risk is one that is a lower confidence
6 interval of greater than one. And you will see an
7 example of one which is not greater than one with the
8 other mouth and pharynx for one to 24 years of use.
9 The relative risk is 1.7, but you see the confidence
10 interval is from 0.4, which would mean a protective
11 effect to 7.2, which would mean a positive risk of
12 over 7.

13 Now, because that interval includes the
14 possibility that the relative risk is one, that is
15 what statisticians say are a nonsignificant
16 association or a nonsignificant relative risk.

17 Q. You are speaking of this figure right here?

18 A. That's the one. Because that brackets one,
19 it is less than one and greater than one, it's
20 nonsignificant, and the last one is the same, 0.5 to
21 2.3.

22 Q. One goes from 9.5 to 9.6, that is
23 technically significant.

24 Q. The figure 1.7, although greater than one --

25 A. Yes.

1 Q. -- still is not significant statistically?

2 A. No significance statistically. And you can
3 see why, one of the reasons why, because the number
4 of cases and controls there is tiny. It is three
5 cases and five controls. So these can easily be
6 chance effects. I mean it could easily instead be
7 four cases and four controls. It wouldn't take very
8 much just to get one more or less control in that
9 sort of sample size.

10 Q. Well, then, from the point of view of
11 determining statistical significance, the larger your
12 study the more reliable it is; is that right?

13 A. Yes. In terms of dealing with chance,
14 random variation, a large study is better than a
15 small one.

16 Q. And what level of confidence was Doctor Winn
17 referring to in her figures here?

18 A. Yes. There are two ways of putting it. It
19 is either 95 percent confidence, or the other way is
20 to call it the 5 percent level of statistical
21 significance. 5 percent of significance and 95
22 percent confidence mean the same degree of
23 confidence.

24 Q. Could you compute a 95 percent confidence
25 level with those figures you have used?

1 A. I could if I could fetch my calculator.
2 Could I do that? Shall I get it from my bag?

3 MR. FINNEGAN: I have got it.

4 (Handed to the witness).

5 THE WITNESS: Thank you.

6 Q. (BY MR. JENNINGS) Doctor, before you start
7 on your calculator, something tells me that since you
8 would only have to change the controls from one to
9 nine, to two to eight, that that can't possibly be
10 statistically significant. Are you going to prove me
11 wrong?

12 A. I will probably prove you right, if you will
13 forgive me, say prove you right. This machine comes
14 all the way from Texas, and it's a relative risk
15 confidence interval calculator, among other things,
16 so you just put in the two numbers -- well, the four
17 numbers. It gives me 2.25, and then the lower limit
18 is not quite 20. It is 28.4, so I think you can see
19 that a small study like that is consistent with a
20 wide range of possibilities, from an enormous
21 protective effect of relative risk of .18 to quite a
22 high harmful effect of 28.48.

23 Q. Now, would the smallness of the numbers
24 involved in Doctor Winn's buccal cancer, people using
25 it more than 50 years or more, would that have any

1 effect also on the reliability of the figures?

2 A. Yes. It gives a very wide confidence
3 interval, ranging from about nine to about 250. So
4 the precision of that estimate, even if the study
5 were totally unbiased, without any problems of
6 confounding, the precision of that statement -- of
7 that risk is obviously very low. It is a very
8 imprecise estimate of what the association is if it
9 exists.

10 Q. Well, am I reading this chart right that by
11 chance the number might have been 9.1 rather than
12 47.5; is that what that means?

13 A. Well, what it means is that if the true risk
14 was really 9.1, you could easily in a small study
15 like this get a false impression by getting a
16 relative risk of 47.5. So the 47.5 might really be a
17 real risk or whatever we mean by that, but the true
18 association could be a relative risk of 9.1 and just
19 because the figures were so small, they look like
20 47.5 in that particular data set.

21 Q. Doctor, are you aware of epidemiological
22 studies that have been done in other parts of the
23 world besides the United States?

24 A. Yes, primarily in India.

25 Q. Do you consider the studies in India to be

1 related in any way to the situation in the population
2 of the United States?

3 A. Well, I think the answer must be "no," for a
4 variety of reasons. First of all, the substance or
5 the substances that Indians use are quite different.
6 They use tobacco sometimes, sometimes no tobacco, but
7 they usually use leaves, I think pan is one, mix
8 various substances in it, lime, some nuts, I think
9 betel nuts I think is an odd name for them, they use
10 concoctions which vary throughout India, so they are
11 really quite different from the sort of tobacco
12 products used in the United States or Europe.

13 The second thing is that obviously Indian --
14 an Indian population are substantially different
15 racially from populations in Europe and the United
16 States, and what we know from the Winn Study, she
17 found, for example, that the relative risk estimates
18 from the Black center study were quite different from
19 the relative risk estimates in the white study.

20 Now, if you can get two races living in the
21 same country having a difference, two races who
22 happen to live in two different countries, the
23 comparability, the relevance of one to the other must
24 be minimal.

25 The third thing is that Indians have quite a

1 different lifestyle from Europeans. A large
2 proportion of them are vegetarians, for example. And
3 there is one study from India which found that risks
4 of oral cancer from chewing various substances were
5 confined to those who did not eat meat, fish or eggs,
6 even confined to vegetarians. So I think that the
7 relevance of data on a different population with a
8 different lifestyle using different substances to the
9 United States and Europe is very, very tenuous.

10 Q. What about variations within India itself?

11 A. Well, to call the country India is like
12 calling England Europe, in that there are a large
13 variety of cultures within India, and the variation
14 in rates of oral cancer within India is tremendous.
15 And I think they can't even extrapolate from one part
16 of India to another part of India, so extrapolation
17 outside India must be even more difficult.

18 MR. JENNINGS: If the Court please, I wonder
19 if it would be convenient at this time to take our
20 afternoon recess so I may consult with counsel and
21 perhaps see how close we are to finishing.

22 THE COURT: That will be fine.
23 We will take our afternoon recess, ladies and
24 gentlemen. We will recess for 20 minutes. Everyone
25 remain seated while the jury exits for 20 minutes.

~~Court will be in recess.~~

1 THE COURT: Be seated.

2 MR. JENNINGS: Thank you, Your Honor.

3 THE COURT: Go ahead, Mr. Jennings.

4 Q. (BY MR. JENNINGS) Doctor Macrae, in order
5 that we not have any confusion about the charts, what
6 does a zero mean under "case, snuff use"?

7 A. It means the case was not a snuff dipper and
8 never had been.

9 Q. Zero is a nonuser?

10 A. A nonuser, yes.

11 Q. Over here the zero means that the Control
12 No. 1 was a nonuser?

13 A. Nonuser, yes.

14 Q. What does the one mean?

15 A. One means -- one means sometime in the
16 case's life the case had been a snuff dipper.

17 Q. So for No. 3, here which is ID 41, the case
18 was a snuff user, Control 1 was a snuff user, --

19 A. Yes.

20 Q. -- Control 2 was a snuff user?

21 A. Yes.

22 Q. The case did not smoke?

23 A. Yes.

24 Q. And Control One did not smoke?

25 A. Correct.

1 Q. Control 2 did not smoke?

2 A. Yes.

3 Q. In effect, one means yes and zero means no?

4 A. That's the meaning of that, yes.

5 Q. Doctor Macrae, do you recall the statement

6 in the Winn paper in the New England Journal of

7 Medicine that about one-third of the subjects started

8 the habit at age 10 or younger?

9 A. Started to dip snuff at the age of ten or
10 younger.

11 Q. Yes, sir.

12 A. Yes, I do recall that.

13 Q. And is that borne out by your charts? This
14 is just tongue cancer we are talking about here?

15 A. Yes.

16 Q. And she was referring to the entire study?

17 A. Yes, a substantial number of the cases are,
18 I think about 36 percent is the actual figure, are --

19 Q. Does this figure indicate that the user
20 started at age 5, that the case over here, 22, --

21 A. That's correct.

22 Q. -- started at age 5?

23 A. Yes.

24 Q. This one started at age 5?

25 A. Yes.

1 Q. And the controls, this one started at age 8
2 and this is age 6?

3 A. That's exactly right.

4 Q. This one at age 6?

5 A. Yes.

6 Q. This one at age 5?

7 A. That's right.

8 Q. Now, with regard to your death certificate
9 cases, you see here is a case that began at age 10,
10 another one at age 10?

11 A. Yes.

12 Q. The Control at age 7, 8, 9; is that correct?
13 Is that what those figures show?

14 A. Yes, indeed, that's true.

15 Q. Now, if we are talking about a study that
16 was made between 1975 and 1978, --

17 A. Yes.

18 Q. -- then if somebody began using snuff, for
19 instance, at age 5 here and is now -- or at the time
20 is 76 years old, that would indicate that the
21 beginning date had been 71 years ago?

22 A. That's right, yes.

23 Q. And that would mean that if that person was
24 studied in 1976, that she began using snuff in 1905?

25 A. That's what the figure says, yes.

1 Q. And, of course, she didn't start because she
2 saw Walt Garrison on TV?

3 A. I think that would be difficult in 1905.

4 Q. Now, once again, all cases had cancer and
5 all controls did not have cancer?

6 A. That's correct, yes.

7 Q. That's the way the study was set up?

8 A. Yes.

9 Q. Have you made a computation of the relative
10 risk as to all cases in the Winn Study?

11 A. Everybody.

12 Q. Yes.

13 A. The relative risk is just under 2, if you
14 put all types of cases together.

15 Q. That is, if you don't eliminate anybody, you
16 just take all of them?

17 A. If we take everybody.

18 Q. And you take all sites,--

19 A. All sites, yes.

20 Q. -- including the buccal mucosa, the gums,
21 where you had a very high relative risk?

22 A. Yes. If you pool them into the total and
23 count the relative risk, regardless of site, it is
24 under two.

25 Q. Now, you made the statement that there was a

1 difference as far as the Winn Study was concerned
2 that Doctor Winn had found a difference as to Black
3 users and white users; is that correct?

4 A. That's true, yes.

5 Q. What difference did she find?

6 A. She found that the association was much
7 weaker in Black users, that it was white users who
8 had the higher relative risks than Black users.

9 Q. All right, sir. Now, Doctor Macrae, as a
10 scientist, what does the Winn Study establish as far
11 as you are concerned with regard to the relationship
12 between tongue cancer and the use of snuff?

13 A. It -- inasmuch as it is a
14 reasonably well-conducted case control study,
15 possibly as good as was practical, it demonstrated
16 that there was, in effect, no statistical association
17 between tongue cancer and snuff-dipping.

18 Q. And if another scientist had analyzed the
19 study the same way you did with regard to tongue
20 cancers, would he necessarily come to the same
21 conclusion?

22 A. I think he must, because there just aren't
23 enough snuff dipping cases, or an equal number,
24 approximately, of snuff-dipping controls, and the
25 numbers are capable of no other interpretation.

1 MR. JENNINGS: Thank you, sir.

2 THE COURT: Cross-examine.

3 CROSS-EXAMINATION

4 BY MR. BRALY:

5 Q. Doctor Macrae, how far did you come to
6 testify in this trial?

7 A. I'm from London. I don't know the precise
8 mileage, I'm afraid.

9 Q. Do you know where the United States Tobacco
10 Company is located?

11 A. I don't actually know.

12 Q. You do understand we are here in the United
13 States?

14 A. I understand that, yes.

15 Q. Will you tell the jury why they had to go
16 all the way to England to find a statistician to come
17 to Oklahoma to testify?

18 A. I can't comment on what the thinking was
19 behind that.

20 Q. Doctor Macrae, do people in England commonly
21 use snuff in the mouth?

22 A. Not very commonly, no.

23 Q. Do you have children?

24 A. No.

25 Q. Would you recommend that children use snuff?

1 A. I wouldn't give a positive recommendation
2 that they should, no.

3 Q. Doctor, if you had to characterize the place
4 where your principal experience has been prior to the
5 time that you were hired by the United States Tobacco
6 Company to come and testify as a statistician in this
7 case, how would you describe that experience to this
8 jury?

9 A. I wasn't quite clear about the question.
10 Was it where my experience was? Does that --

11 Q. What was the nature, what has been the
12 nature of your work since you have been out in the
13 real world?

14 A. Yes. It's been dealing with statistical
15 aspects of medicine generally.

16 Q. Can you be a little more specific?

17 A. Yes. That most medical research that is
18 clinical or epidemiological generates data, and my
19 role has been to advise people before they collect
20 the data as to how they should conduct the research
21 from a statistical point of view and to advise and
22 sometimes undertake the analysis of the numbers that
23 they collect after the study is completed.

24 Q. Am I correct in saying that a review of the
25 articles that you have published in the literature

1 would reveal that the majority of those articles have
2 involved hospital clinical trials to determine the
3 advocacy of various different treatments?

4 A. The majority of the published articles,
5 that's correct.

6 Q. And that very few have in any way been
7 engaged in or involved in the determination of the
8 cause of any disease?

9 A. I would say that I can't think of any
10 article that would be a statistical article that
11 would actually deal with the cause of a disease.

12 Q. So prior to the time -- you did say you
13 couldn't think of any in particular?

14 A. Well, the force of my answer was intended to
15 be that a statistical paper, epidemiological, is not
16 actually primarily dealing with the cause of a
17 disease. It is looking at statistical associations.

18 Q. Well, I understand that epidemiologists have
19 a function which is to try and determine the cause of
20 diseases, and you are not an epidemiologist. You
21 are, sir, a statistician; is that correct?

22 A. In the United States -- in UK terms I am a
23 medical statistician. The term epidemiologist in the
24 UK tends to be applied primarily to doctors who are
25 involved in epidemiological studies.

1 In the United States I think the label
2 epidemiologist would be applied to somebody who does
3 my job.

4 Q. You did come out of the Department of
5 Statistics at the University of Aberdeen?

6 A. Yes.

7 Q. And subsequent to that you did work in
8 psychology and statistics?

9 A. That's correct, yes.

10 Q. Doctor, if one or two examined the published
11 literature would want to find out what you have
12 written, want to go to the computer and sit down at
13 the computer terminal of the National Institutes of
14 Health's med-line service and for a summary of the
15 articles that you have written, couldn't they?

16 A. They could, indeed, yes.

17 Q. And that data base goes back to about 1966;
18 is that your understanding?

19 A. Yes, that's right.

20 Q. And I believe it was sometime after that
21 that you began to publish in the literature.

22 A. Yes.

23 Q. So that such a study should, at least in
24 your case, should turn up everything that you have
25 written that has been published in well-regarded peer

1 review journals?

2 A. Well, not every journal is in all the
3 computer data banks, not all of them.

4 Q. The well-regarded and peer review journals
5 are.

6 A. Most of them would be. I mean I am
7 surprised --

8 Q. Would you give us an example that would not
9 that you consider to be well-regarded in peer review?

10 A. I know that -- I can't quite quote, but I
11 remember my experience in the past has been that
12 looking for certain articles, the journal that I knew
13 had been published and wasn't listed, but I would
14 accept your statement that the majority are.

15 Q. Doctor, what is the significance of being
16 listed as the first author in a publication?

17 A. It can mean different things in different
18 articles. Sometimes it is that your name is rather
19 high on the alphabet, if your surname begins with A
20 or B, and an order of authors is determined
21 alphabetically. That may be the only significance.

22 Sometimes the convention is that it's -- the
23 person often who is the junior person who did the
24 basic straight-forward, what one might call routine
25 work, that, in fact, the most eminent person can have

1 his name last. I think the usage is so variable that
2 to make a general statement is difficult.

3 Q. How many articles would one find if one did
4 a computer search for Kenneth D. Macrae?

5 A. In total, I don't know the number off the
6 top of my head.

7 Q. Would it surprise you if I sat down at my
8 computer terminal last night and asked that question
9 of the National Institutes of Health, there were a
10 total of 57 journal articles out there in the
11 literature that had your name on them?

12 A. I'm not surprised at the number, no.

13 Q. Would it surprise you further that out of
14 the 57, that 13 of them were letters to the editor?

15 A. No, that's quite understandable.

16 Q. Would it surprise you that only
17 approximately four of those had your name listed as
18 the lead author?

19 A. Yes. In medical statistics you usually work
20 with medical colleagues. They usually choose the
21 problem, and in fact they do the vast majority of the
22 actual work. If it is treating patients, doctors
23 treat patients. If it's epidemiological study, the
24 data are collected by doctors and nurses usually. So
25 the role of a statistician is as part of a research.

1 team, but not the whole research team. And the
2 majority of medical statistical work is not done by
3 statisticians by themselves. And also much of your
4 work isn't reflected in publications at all.

5 Q. Doctor, let me hand you an excerpt that I
6 obtained from the Lancet this morning. Would you
7 look at that. Is that another one of your letters to
8 the editor that you wrote into the Lancet?

9 A. Yes, with two other colleagues, that's true.

10 Q. This one mentions head and neck cancer,
11 doesn't it?

12 A. It does, yes.

13 Q. It doesn't discuss the cause of head and
14 neck cancer, does it?

15 A. It doesn't, no.

16 Q. That is one of the 57 that we were referring
17 to; is that right?

18 A. Well, obviously, without a complete list of
19 the 57, there is no way I can check with if that
20 statement is true or false. I independently don't
21 know that fact.

22 Q. Doctor, this represents a list of the
23 research that you have published, that at least you
24 or the people that published the journals considered
25 to be significant, doesn't it?

1 A. I think the statement considered to be
2 significant is one that I don't have an opinion on.
3 I accept this as a list you obtained from the
4 computer which fulfilled the criteria that the people
5 who sat up the data base adopted. And other than
6 that, I have no further comment on that list.

7 Q. Doctor, isn't it true that the bulk of these
8 journal articles in which your name appears deal with
9 either breast cancer or stomach ulcers or
10 reproductive-tract cancers or bowel cancers?

11 A. The majority would fulfill these criteria,
12 yes, that description.

13 Q. And almost all of those deal with clinical
14 trials as to different treatments of these diseases.

15 A. Yes, indeed.

16 Q. So far as you know, not any of them deal
17 with the determinations of causes of any of these
18 cancers?

19 A. I think that's true, yes.

20 Q. As a matter of fact, Doctor, with respect to
21 your experience prior to getting involved in this
22 litigation, if one asked this computer for Kenneth D.
23 Macrae and oral cancer or Kenneth D. Macrae and
24 snuff, Kenneth D. Macrae and tobacco, one will not
25 come up with a single example from the medical

1 literature where the computer will find your name in
2 association with any of those topics, will it?

3 A. I think that's true, yes.

4 Q. I believe that you have just told Mr.
5 Jennings and the jury that you thought that the
6 Deborah Winn Study was a pretty good study?

7 A. It was a pretty good case-control study.

8 Q. And that it provides some statistically
9 useful information?

10 A. I think the word "useful" is a word I would
11 like to have defined before I answer the question.

12 Q. Well, is it good for anything?

13 A. It's good -- good for anything is such a
14 strange way to put it. It can demonstrate whether
15 there's a statistical association between various
16 exposures and habits and -- not oral cancer, head and
17 neck cancer, oral cancer on different sites.

18 Q. Has it established in any way a statistical
19 association?

20 A. The principal statistical association in
21 that study is that between long-term snuff-dipping
22 and cancer of the cheek and gum. The rest of the
23 data is largely negative statistically.

24 Q. But there is a statistical association as
25 far as you can tell between the long-term use of

1 snuff and cancer of the cheek and gum?

2 A. With reservations, the reservation is that
3 the numbers are small and it is a retrospective study
4 with obvious problems that such studies always face.

5 Q. On the face of the data, it does -- I
6 believe you are telling us that it means something,
7 otherwise -- are you telling us that the study, that
8 you can draw no conclusions from the study?

9 A. Well, I think the term "draw conclusions" is
10 so nonspecific that I'm not sure how I can answer
11 that. I have answered what I think is my conclusion
12 that there is a -- an apparent statistical
13 association which one would treat with some
14 reservations for some of the reasons I have explained
15 when Mr. Jennings was asking me questions, but the
16 data -- the association in that study is largely
17 confined to that part of the data, long-term
18 snuff-dipping with cancer of the cheek and gum.

19 Q. A nine-fold, even at the lower limits of the
20 confidence interval, a nine-fold increase in the risk
21 is of some considerable concern to ordinary human
22 beings, isn't it?

23 A. Well, nine-fold -- the figure nine takes
24 account of chance being the only reason why the risk
25 would be wrong. And, of course, in a retrospective.

1 study, chance is not the only reason. If you don't
2 interview the study subjects themselves, if you
3 interview them long after they developed the disease,
4 by people who know the diagnosis, can you really say
5 that four dippers means four and shouldn't be six or
6 it shouldn't be three, is putting an awful lot of
7 confidence in very weak soft data.

8 Q. And that is because the numbers are small?

9 A. It is also because the data are
10 retrospective.

11 Q. But you have told us that it is the best
12 that can be done because it is impossible to do a
13 prospective study?

14 A. Well, I didn't say the Winn Study is the
15 best possible case control study. It might be
16 possible and, indeed, Doctor Winn herself, I believe,
17 at one time said she was going to undertake a further
18 study, it might be possible to do a better case
19 control study. What I am saying is that Doctor
20 Winn's first study, this one, was a relatively good
21 study, but a cohort study, if it was possible, a
22 prospective study, if it was possible, would be much
23 better.

24 Q. And a relatively good study, as you just
25 described Doctor Winn's study would not be one that

1 had any reasonable conviction attached to it, would
2 it?

3 A. Any reasonable --

4 Q. Conviction attached to its results?

5 A. I didn't quite catch -- Was it restriction,
6 did you say?

7 Q. You did say that you thought Deborah Winn's
8 study was a reasonably good study?

9 A. It is a reasonably good study, yes.

10 Q. You would not characterize a study that was
11 reasonably good as one that does not have some
12 reasonable conviction attached with it?

13 A. Again, I have difficulty understanding what
14 you mean by reasonable conviction.

15 Q. You don't understand what those words mean?

16 A. Well, they are not scientific or
17 epidemiological or statistical terms which are
18 defined, so I would need you to explain the meaning
19 of that term before I could answer it.

20 Q. You wouldn't use those terms when you were
21 trying to convey important information to people
22 because you don't understand them?

23 A. No, because I think that when you use common
24 parlance in a technical way, people might understand
25 different things by the term, and what you mean by

1 conviction, reasonable conviction, and what an
2 epidemiologist means by it might be totally
3 different, so I wouldn't be sure I would be answering
4 the question I understood.

5 Q. So you basically would not use those words,
6 because you don't think that they have any common
7 understanding?

8 A. I'm not making a general statement that I
9 would never use the word "reasonable conviction." I
10 am saying in the context of talking about the Winn
11 Study, I wouldn't describe it in that way.

12 Q. Fine. Doctor, do you recall being asked to
13 testify before the Congress of the United States --

14 A. Yes, I do.

15 Q. -- about a year ago?

16 A. Yes, I do, yes.

17 Q. And did you do that?

18 A. Yes, I did.

19 Q. And, Doctor, at that time, as opposed to
20 this time, didn't you in fact use those precise words
21 when you were representing the smokeless tobacco
22 industry in front of the Congress of the United
23 States?

24 A. I'm sure if you are asking me the question
25 that I did. I don't know how.

1 Q. I am quite sure that you did. As a matter
2 of fact, didn't you make the statement with respect
3 to the Winn Study, I believe it is found at Page 346
4 of the, report of the hearings of the subcommittee on
5 health and the environment, "That study has not even
6 established with reasonable conviction a statistical
7 association."

8 But now you tell us today that it is a
9 reasonably good study? Why have you changed your
10 mind?

11 A. Because I -- I haven't changed my mind.

12 Q. It is a reasonably good study but it
13 establishes nothing with reasonable conviction?

14 A. I didn't say it establishes nothing. What I
15 said was it establishes with due reservation that
16 there is an association for one particular site in
17 the mouth, i.e., the cheek-gum site, for very long
18 term use, but that that association, because of the
19 fact that it was obtained by selecting very carefully
20 the case and controls on which it was based is one
21 which one would treat with caution.

22 Q. Doctor, you have criticized here today the
23 use of data from third persons to obtain the
24 histories on these people, haven't you?

25 A. Yes. I have considered it potentially --

1 Q. In your opinion it is much less desirable to
2 use the data from relatives than it is to obtain
3 first-person information?

4 A. I think generally in epidemiology one would
5 say that would be the case; however, there may be
6 aspects of the individual subject which make them
7 less suitable than a relative under certain
8 circumstances.

9 Q. Doctor, specifically with respect to the
10 Winn Study, you have severely criticized that study
11 for relying on just exactly that kind of data?

12 A. Well, the real reason for the criticism is
13 that if all the cases and all the controls had been
14 personally interviewed or if none had been, that
15 would, at least, have been even, evenhanded, but the
16 fact, the real problem with the Winn Study is what
17 one would call bias, ascertainment bias in that much
18 fewer of the cases were interviewed personally than
19 the controls. That is a difference in the way the
20 data was obtained between the cases and controls. It
21 is a lack of equality.

22 Q. Doctor, it would be possible to go through
23 the data and consider only those cases where there
24 was first-person information and only those controls
25 where there was first-person information?

1 A. It would indeed yes.

2 Q. Doctor, you criticized the Winn Study
3 because it included this other kind of data from
4 third persons, didn't you?

5 A. Yes, unequal portion in the cases and the
6 controls.

7 Q. In fact, in your testimony about the
8 Congress of the United States, you mentioned the
9 inherent methodological weaknesses in the study.
10 Didn't you, Doctor, say that this means that in a
11 majority of the study subjects the data was obtained
12 from third parties?

13 A. Yes.

14 Q. And later on, of course, a major source of
15 bias was introduced because unavoidably this
16 information was obtained from third parties after the
17 occurrence of the disease was already known by the
18 investigators and study subjects, and the third
19 parties providing the information?

20 A. Yes, yes.

21 Q. You focused quite heavily on this
22 third-party aspect of the data, didn't you?

23 A. Yes, I did, yes.

24 Q. Having focused quite heavily upon it, you
25 nevertheless, and apparently you have got this data.

1 available to you and have had for some time, you have
2 not gone back and made that calculation to find out
3 what would happen if you only focused upon the first
4 part of your data and information, have you, Doctor?

5 A. I have looked at that, yes.

6 Q. And what did you find when you had a look at
7 that, Doctor?

8 A. The main finding was that the cases who were
9 interviewed personally give a similar rate of snuff
10 usage to cases for whom the data was obtained from a
11 third party, but with controls there was a
12 difference. Strangely enough, a higher rate of snuff
13 users supported for controls who had the data
14 obtained from a relative rather than from controls
15 who were interviewed personally. So --

16 Q. People were lying about their snuff habits,
17 weren't they?

18 A. I won't say they were lying. I am saying
19 you get a difference in the rate of snuff usage,
20 depending on how you got the data from the controls.
21 So this clearly demonstrates that how you get the
22 data makes a difference. The trouble being a
23 retrospective study is, you don't know what's true.
24 You don't know if the people themselves are reporting
25 less than the truth. You don't know if the relatives

1 are reporting more than the truth or what. It's an
2 uncertainty. That is the nature of a retrospective
3 study.

4 Q. Doctor, did you stop and make the
5 calculations of the relative risks considering only
6 first-person data?

7 A. No, I didn't, no.

8 Q. Is there some reason why you didn't bother
9 to do that when you went to all this other trouble?

10 A. Yes. The reason is that when you try to do
11 that, you sometimes get a case who is interviewed
12 personally matched with controls that weren't, or you
13 get a case that was interviewed personally matched
14 with controls that were, and it becomes extremely
15 complicated.

16 And the second reason is that the hearing
17 before the Congress of the United States was on the
18 general issue, whereas my analysis for this
19 particular trial was obviously to make it relevant to
20 the particular case being tried, and the relevance
21 here is to do the tongue cancer.

22 Q. Doctor, you are a statistician
23 fundamentally; is that correct?

24 A. Yes.

25 Q. Not a medical doctor?

1 A. That's correct.

2 Q. I don't want to run this long litany. Mr.
3 Jennings has done that previously in this trial. You
4 cannot tell us one way or another whether the causes
5 of cancer of the mouth have some etiologically common
6 factor?

7 A. I can't tell you that, no.

8 Q. So the causes of tongue cancer may be the
9 same as the causes of any other cancer of any other
10 mucous membrane inside the oral cavity? You don't
11 know that one way or another, do you, Doctor?

12 A. Given that I think nobody knows the cause of
13 cancer, that may not be true.

14 Q. Now, you were telling this jury that nobody
15 knows the cause of any cancer?

16 A. I think we have a better or the medical and
17 scientific community are closer to understanding some
18 cancers than others.

19 Q. But the answer to my question is "yes," we
20 do not understand?

21 A. I think that question, given the nature of
22 scientific knowledge, is not capable of a sweeping
23 statement answer like that.

24 Q. At any rate, you don't know what the causes
25 of oral cancer are, do you?

1 A. No, I don't.

2 Q. Other than looking at these statistics in
3 this case, at least, you have not published any work
4 that purports to investigate the causes of oral
5 cancer?

6 A. That's true.

7 Q. You really haven't done any such study in
8 fact, have you?

9 A. No, no, that's true.

10 Q. So as you sit here today, you really can
11 provide this jury with no useful information on the
12 causes of oral cancer.

13 A. That's not true. I can give the jury
14 further information on Doctor Winn's data on the
15 specific type of cancer, which is relevant to this
16 case.

17 Q. But I think what you said a minute ago was,
18 Doctor, that you didn't know whether the same things
19 that caused tongue cancer cause other cancers of the
20 mouth.

21 A. I don't know, but what I would say is if
22 epidemiology is of use at all, it would -- the
23 associations in epidemiology, if they are positive,
24 may reflect causation. They may reflect something
25 else. If there are no associations, it makes it

1 rather difficult to say that that there is a link
2 there at all. If there is strong associations for
3 some sites and no associations for others, it would
4 at least suggest that there might be a different
5 etiology, a different causation for one site as
6 opposed to another.

7 Q. Doctor, you don't even think that smoking
8 has been shown scientifically to be a cause of lung
9 cancer, do you?

10 A. I think ultimate proof of that still hasn't
11 been achieved.

12 Q. The answer to my question is that Kenneth
13 Macrae does not think it has been scientifically
14 shown that smoking causes lung cancer.

15 A. That's right.

16 Q. Given the vast number of studies that have
17 been done on that subject, I take it that you would
18 think it would take an equally vast number of studies
19 done on the subject of snuff dipping before you would
20 reach the same conclusion that no such cause has been
21 established?

22 A. Well, no. I think the actual number of
23 studies is not the point. It's the nature of the
24 studies. If you are looking at this issue primarily
25 or exclusively from the point of view of statistical

1 association, that will not deal with our question of
2 causation. You have to wait until scientific
3 knowledge achieves a basic understanding.

4 Q. I want to come back to that after a while.
5 But in the meantime, Doctor, going back to this issue
6 of these very etiological factors that cause oral
7 cancer, if we don't know that one of them is or is
8 not a cause of tongue cancer as distinguished from
9 some other cancer of the mucous membranes, there is
10 no reason then not to lump those sites together, is
11 there?

12 A. Well, you could take that view, in which
13 case the shortest in Doctor Winn's own opinion,
14 epidemiologist, the strongest reason that has been
15 advanced by the Surgeon General, by the consensus
16 conference and so on for thinking the Winn Study is a
17 strong study and that it may -- its association may
18 suggest causation in the opinion of various people,
19 is that for this specific site, gum and buccal, this
20 relative list, which is widely said to be almost 50
21 has been achieved.

22 Now, if you are criticizing me for selecting
23 the tongue and not taking all of the mouth sites,
24 perhaps you should be criticizing Doctor Winn on all
25 the people who quote a study for selecting that

1 relative risk of almost 50 and quoting it in
2 isolation. It is not even all gum and buccal cases.
3 It is only those who are from the hospital that
4 sample who are nonsmokers and who have snuff dipped
5 for more than 50 years. Now, it would seem that my
6 error in looking at all the tongue cases is much less
7 than the error of quoting that 47.5 as the figure
8 from the Winn Study.

9 Q. What about the error of not simply quoting
10 what Doctor Winn quoted and stated that "the relative
11 risk associated with snuff dipping among white
12 nonsmokers was 4.2"?

13 A. Well, --

14 Q. That's a fairly all-inclusive statement,
15 isn't it? It includes everybody except the smokers
16 and the Black folks.

17 A. I think you might well find it excludes the
18 deaths as well. I think that is the hospital sample.

19 Q. And, of course, you criticized the death
20 certificates for being less reliable, so you are now
21 criticizing her for using the reliable information
22 and arriving at this figure?

23 A. Well, the death certificates, all the death
24 certificates --

25 Q. Excuse me. Let me divide the question. You

1 have critized her for relying upon death certificate
2 data? You have done that, sir?

3 A. Can you remind me of in precisely what words
4 I do so?

5 Q. I think you did it in front of the
6 Congressional hearings. You mentioned that that was
7 one of the limitations, and I also think you did it
8 in your testimony today when you mentioned the
9 limitations or death certificates.

10 A. There are clearly difficulties with death
11 certificates, but --

12 Q. Doctor, flat out, isn't it better to use the
13 hospital cases than the death certificates because
14 you have got better records from the hospital?

15 A. There is a fundamental difficulty here. If
16 you have a disease that kills some people but doesn't
17 kill others, if you take just today or you take just
18 the dead, you get a biased sample of the disease.

19 Now, if you got an exposure which made you
20 less likely to die if you got the disease and you
21 only looked at the survivors, it would appear to
22 produce a relative risk which was because the agent
23 was actually protective. An example of this might be
24 with heart attacks. Some people die when they have
25 their first heart attack, and some people survive

1 it. Supposing exercise protected you against dying
2 if you had a heart attack, and you only look at
3 survivors of a latter attack, it will make it look as
4 if exercise increased your risk of having a nonfatal
5 heart attack, and it does this because it prevents
6 you from dying.

7 So you must take a representative sample of
8 all cases. You can't just look at the living or just
9 the dead, or you get a biased sample. It's the way
10 the data has to be obtained that is the problem, not
11 the fact that the cases are live or dead.

12 Q. Doctor, irrespective of your estimate, it is
13 true that Doctor Winn said that "the relative risk
14 associated with snuff dipping among white nonsmokers
15 was 4.2"?

16 A. She said that, yes.

17 Q. And that's what her numbers bear out. You
18 are not saying that her numbers are wrong, are you?

19 A. That's what some of her numbers, that she
20 leaves out the one she did in that calculation there.

21 Q. Are you telling us that those are?

22 A. Well, if it is white nonsmokers, she leaves
23 out all the smokers and all the Blacks.

24 Q. Is there some reason why she would
25 deliberately leave out the smokers, Doctor?

1 A. Yes, because the smokers give a lower
2 relative risk.

3 Q. Yes, they confound the matter, don't they?

4 A. They do, indeed.

5 Q. They confound the matter because any time
6 that you introduce multiple causes into a
7 case-control study, it generally --

8 As a matter of fact, you can prove it
9 mathematically, that it will cause the results to be
10 lowered, won't it?

11 A. No, I think that general statement is not
12 true.

13 Q. Doctor, she didn't include smokers because
14 smoking itself may be a cause for oral cancer; right?

15 A. May be, yes.

16 Q. Right. And so she wanted to study
17 nonsmokers who were snuff dippers?

18 A. Well, no. I -- I think you got that wrong.
19 She didn't want to study nonsmokers. She obtained
20 the sample of cases which included smokers and
21 nonsmokers and the same with the controls, and she
22 analyzed all the cases and controls, regardless of
23 smoking, and then she analyzed them separately.

24 And one of the interesting things about the
25 data is if we take the hypothesis that snuff causes

1 oral cancer and smoking causes oral cancer, would
2 somebody who is exposed to both be expected to be a
3 lower risk than somebody that is exposed to just one
4 or a higher risk? Now, the most plausible, I think,
5 the biologically plausible thing is if you are
6 exposed to two causes of cancer instead of one, you
7 should be more likely to get cancer. The Winn Study
8 showed the opposite.

9 Q. Doesn't smoking tend to cause cancers
10 further back in the mouth and cancers of the lung as
11 opposed to cancers of the mouth?

12 A. You used the word "smoking causes cancer."

13 Q. I understand we have got a fundamental
14 problem with the definition of terminology, because
15 you don't think anything causes cancer, do you?

16 A. I'm sure something must.

17 Q. But you can't tell anybody in this courtroom
18 what it is?

19 A. No, I can't tell them what it is.

20 Q. So in terms of causing cancer, so far as you
21 are concerned, it would be safe for people to stand
22 around the radiation exposure, for instance, from
23 nuclear power plants because radiation is not a cause
24 of cancer. Isn't that just what you told us, Doctor,
25 that you can't tell us anything that causes cancer?

1 A. Well, there are two things to say. First of
2 all, I can't tell you anything is safe. To prove
3 safe, yes, actually impossible. And second,
4 radiation, of course, I don't dispute for one instant
5 that radiation has a very high risk of producing
6 cancer. And I think that actually, now that you
7 brought it to my attention, that is something I
8 wouldn't challenge, for instance.

9 Q. Now, the reason you say that we don't know
10 what causes other cancer is because we don't
11 understand the mechanism by which cancer is produced?

12 A. There is more to it than that actually,
13 because I think that very occasionally there are
14 examples of statistical associations which have no
15 other conclusion than that a causal link exists, even
16 though we don't know the mechanism.

17 Q. Doctor, are you saying we have to rule out
18 every other possibility before we can reach a
19 rational judgment?

20 A. No. What I am saying is that some diseases
21 are more difficult to pin down in terms of causation
22 than others.

23 Q. Doctor, you didn't mention the mechanism
24 problem as the reason why we don't understand the
25 cause of oral cancer.

1 A. Given the statistical evidence, it was the
2 only way to proceed, because oral cancer occurs in
3 people, if we are talking about tobacco exposure of
4 various sorts, it occurs in people who have no
5 tobacco exposure and it doesn't occur in everybody
6 that is exposed to tobacco, so that it's completely
7 different from a situation where a disease never
8 occurs in the absence of some agent.

1 Q. The same is true with radiation exposure.
2 Aren't you applying a double standard? You are
3 saying I know that radiation sometimes causes cancer
4 in humans, but I do not understand that mechanism.
5 That is a true statement and you would adopt it,
6 wouldn't you?

7 A. I'm -- in fact, even as a statistician I am
8 not a radiation biologist. I think the mechanism by
9 which radiation causes cancer is actually fairly well
10 understood, but the ionizing --

11 Q. Would it surprise you that you are the first
12 scientist in this court that even pretends to
13 understand that there is a mechanism for any cancer?

14 A. Well, I think with radiation -- and clearly
15 it is foolish of me to pontificate on a subject I am
16 not an expert on.

17 Q. Now, Doctor, the point to my question is
18 that you don't know what the mechanism is by which
19 radiation causes cancer, do you?

20 A. No, I don't.

21 Q. You don't know what the mechanism is by
22 which tobacco causes cancer, do you?

23 A. I don't know of a mechanism which could
24 explain that, if it's is true.

25 Q. You don't know of any such mechanism?

1 A. I don't.

2 Q. Doctor, did you read Doctor Winn's study?

3 A. Did I read it? Yes, yes, I read it.

4 Q. Did she suggest any mechanism which would
5 cause cancer?

6 A. I think the word "mechanism" is not the word
7 I would choose to use. She suggested an explanation
8 or a hypothesis.

9 Q. And what was that?

10 A. Some chemical constituent of tobacco.

11 Q. Do you know what those are?

12 A. I have read their names, but I am not a
13 chemist, so they don't mean much to me.

14 Q. So if those chemicals have something to do
15 with the mechanism by which cancer is caused, then
16 you don't have any knowledge or understanding of
17 that?

18 A. That's true.

19 Q. And, Doctor, would it's surprise you to find
20 that there are carcinogenic chemicals in snuff?

21 A. I would -- I, in fact, would be silly to
22 have an emotional reaction to that since it is a
23 surprise, because I can't define a carcinogenic
24 chemical. I have no independent way of assessing
25 what a carcinogen is. That sort of information lies

1 in another type of expert's field. My understanding
2 is confined to statistical issues.

3 Q. Doctor, the reason I asked you that question
4 was because I had asked you the question earlier
5 about the fact that -- I was taking issue with you
6 having isolated the tongue cancers away from the rest
7 of the cancers of the mucous membranes of the mouth.
8 You recall that?

9 A. Yes, I do.

10 Q. You recall I was asking some rather pointed
11 questions as to why that was proper for you to take
12 this onion and keep slicing it until you could find
13 no longer any statistical significance. That was my
14 criticism of what you had been doing; right?

15 A. Well, I don't recall you mentioning onions
16 at the time.

17 Q. True, I didn't.

18 A. No.

19 Q. But it seems like since this case has begun
20 that it has been the strategy of the U.S. Tobacco
21 Company to take this onion and slice it and slice it
22 and slice it until they can try and ultimately get
23 something they can see through and say, "Ah-ha, there
24 is nothing here." It seems to me that is what you
25 have done by trying to take a study which in itself.

1 focused on oral cancer.

2 MR. JENNINGS: If the Court please, I wonder
3 if that is a question or whether counsel was arguing.

4 THE COURT: Sustained. Ask a question,
5 counsel.

6 Q. (BY MR. BRALY) Doctor, isn't it true that
7 Doctor Winn's study focused on oral cancer?

8 A. Since you asked the question, not quite.

9 Q. That was the title of the article, wasn't
10 it?

11 A. She left out certain sites.

12 Q. Snuff-dipping and oral cancer among women?

13 A. Some oral cancers, oral specified.

14 Q. She did use other mouth, didn't she?

15 A. Mouth sites were defined. She, for
16 example, explicitly omitted one site.

17 Q. She explicitly omitted a number of sites,
18 because there wasn't --

19 Q. Which are included, which are included in
20 ICD quoted for oral cancer. She specifically
21 included and then she specifically analyzed
22 separately gum and buccal.

23 Q. Yes. That's because she had adequate
24 numbers to do that with, isn't it?

25 A. She had 50 in gum and buccal and she has 50

1 tongues, the same number.

2 Q. She had 50 gum and buccal that were
3 cigarette smokers or nonsmokers?

4 A. A mixture.

5 Q. The point I am trying to make, Doctor, is
6 that if you look at the nitrosamines that the jury
7 has seen some considerable testimony about, all of
8 which are found in snuff, five and seven which are
9 found in highest levels in Copenhagen brand snuff
10 that this young man used, the evidence has been in
11 this case that when those nitrosamines are applied by
12 painting the inside of the mouths of laboratory
13 animals, they cause tumors of the cheek and gum, they
14 cause occasionally a tumor of the tongue. They cause
15 tumors of the mucous membranes to the mouth.

16 Now, in light of that evidence, why would
17 you try and resubdivide this until you could find
18 numbers that by your own testimony are statistically
19 insignificant?

20 A. Oh, I think there are only three reasons.
21 One is animals. Second is chemicals and not snuff.
22 The third is because Winn herself used a subdivision
23 of the cases as one of the strongest arguments to get
24 people to believe the association. There is actually
25 a fourth reason, which is that in terms of proximity

1 to the exposure, suppose, just suppose, that physical
2 contact between the snuff and the tissue was required
3 for harmful effects. Would you dilute the real risk
4 by including lots of irrelevant sites?

5 Q. I wouldn't. Doctor, let me ask you another
6 question. Did you in this elaborate preparation
7 that you made for this trial try and further slice
8 the onion and consider the tongue cancers in
9 nonsmokers?

10 A. Yes, yes.

11 Q. You haven't presented that calculation or
12 that data to this jury, have you?

13 A. Oh, I guess I have actually. You can see
14 the nonsmoking tongue cancers there. The smoking
15 and the nonsmoking cases are all presented in that
16 the ones with the zero in the smoking column are the
17 nonsmoking tongue cancers.

18 Q. Yes, the data is there, but you haven't
19 presented the calculation, have you, Doctor?

20 A. No. I have presented -- I haven't really
21 presented any calculations here. I have just showed
22 that the numbers of snuff dippers are --

23 Q. You told the jury what the relative risk was
24 when it was confounded by smoking, didn't you?

25 A. For all cases, yes.

1 Q. But you did not tell the jury what the
2 relative risk was when you compared nonsmoking snuff
3 dippers to nonsmoking controls?

4 A. No, I didn't. It produces a much smaller
5 number, and I think -- I think it doesn't alter the
6 conclusion.

7 Q. You said it produces what?

8 A. It doesn't alter the relative risk to any
9 important degree. You get the same conclusion,
10 whether you do the nonsmokers alone or the all cases.

11 Q. The result you came out with for the tongue
12 cancers confounded by smoking was -- among the
13 hospital cases -- was a risk of approximately 1.1?

14 A. Approximately. I can't give you the exact
15 figures.

16 Q. What is the risk that came out that you
17 didn't tell the jury about for the tongue cancers
18 among nonsmoking people?

19 A. I think it was very similar, but I can't
20 recall the precise figure.

21 Q. You don't recall that number then, do you?

22 A. No, I don't.

23 Q. Have you checked with Deborah Winn to see if
24 she had done that calculation?

25 A. I haven't checked with Deborah Winn, no.

1 Q. Now, have you checked with Deborah Winn to
2 see that if she took into consideration the criticism
3 that you leveled at her study when you testified in
4 front of Congress with respect to reliance upon
5 third-party interviews, have you checked to see what
6 that does to the data when she only considers
7 first-party data?

8 A. I can tell you without asking Deborah Winn,
9 because what it must do as the controls are
10 different, if they are interviewed directly and the
11 cases are not, and the controls report lower use of
12 snuff usage, what it must do is to make the relative
13 risk higher if the cases are interviewed themselves,
14 than if -- the cases and the controls are both
15 interviewed than if neither is interviewed. I must
16 do that.

17 Q. Doctor, I don't understand you. You stood
18 up in front of the Congress and you criticized the
19 study because she considered and relied upon this
20 third-party data, but then when she goes back and
21 takes her data and tries to accommodate your
22 criticism by considering only the first part of the
23 data, you are now criticizing her for doing that.
24 Can't she do anything right?

25 A. She has done a lot of things right, but the

1 nature of retrospective data is that whatever the
2 source, there are imponderable biases, and if you
3 have substantially different sources for the cases
4 than the controls, again that is a difference which
5 may at least in part explain the relative risk.

6 And this, in fact, is what is part of the
7 explanation in the Winn Study, because a larger
8 proportion of her controls were interviewed
9 personally than the cases. I noticed the controls
10 interviewed personally report a lower use of snuff
11 than the controls for whom the data was obtained
12 secondhand. That is going to elevate the relative
13 risk for the total study, and it's also going to give
14 a higher relative risk when you take the case control
15 comparison based on the study subjects themselves
16 being interviewed. They must do that.

17 Q. I think I understand what you are telling
18 me is that when Doctor Winn did the calculations that
19 you suggested by excluding the third-party
20 information, just relying upon this highly reliable
21 first-party information, that the results of her
22 study became much more impressive.

23 A. The association became stronger, that's
24 true.

25 Q. Yes, it did. And, as a matter of fact, I

1 believe you mentioned to the jury a minute ago that
2 it was peculiar, I think you did this, if I recall,
3 with respect to your criticism of the Indian studies
4 that were done in the subcontinent of India, that you
5 mentioned that, gee, you know, we have got this big
6 variation in rates in the results of the Winn Study
7 here in the United States, that is some reason why we
8 shouldn't look at the time Winn Study. Do you recall
9 that testimony?

10 A. Yes.

11 Q. Do you know what the results are of Doctor
12 Winn's study if you go in and look at the
13 first-person data obtained from Black people?

14 A. It seems this onion has been sliced quite
15 thinly now. I wouldn't look at Black people with
16 first-person data as a separate subgroup.

17 Q. Doctor, would it surprise you to find out
18 that when she considers only first-person data, that
19 the relative risk for whites is 5.6 and that the
20 relative risks for Blacks is 5.0? Does that surprise
21 you?

22 A. Not particularly.

23 Q. Did you know that in fact Doctor Winn had
24 presented that data in public?

25 A. I think the --

1 Q. Doctor, my question is did you know that?

2 A. I don't recall these particular figures.

3 Q. Did you know that she had presented those
4 calculations in general in public at the Banbury
5 Conference?

6 A. The which conference?

7 Q. Banbury.

8 A. I don't know a conference by that name.

9 What --

10 Q. Did you know that the Surgeon General of the
11 United States had picked up that information and
12 included that reference in the report of the Surgeon
13 General issued about six weeks ago?

14 A. Oh, the 1986 --

15 Q. Yes.

16 A. --typescript report. I haven't read that in
17 outline. If this is recent, further subdivisions of
18 the Winn data, I probably haven't looked at that in
19 any detail.

20 Q. But you had the data and you could have done
21 that before you came and testified today and made
22 that somewhat misleading statement about Blacks.

23 A. I was presenting the statement about Blacks,
24 which Winn herself presented in her publication in
25 her thesis.

1 Q. Doctor, when it served your purpose, you
2 came into this courtroom and recalculated Winn's
3 data, but when it served your purpose, you quoted
4 Doctor Winn without running the same calculations?

5 A. I think that's not quite it. What I
6 recalculated was the specific cancer site, which was
7 relevant to this case.

8 Q. Doctor, isn't it true that by your own
9 testimony before the Congress of the United States,
10 you said this study can't say anything about tongue
11 cancers?

12 A. I think it's because it is a retrospective
13 case-control study, not very strong data. It can't
14 be strong data.

15 Q. As a matter of fact, Doctor, if we rely upon
16 your statements to the Congress of the United States,
17 the jury will have to come to the conclusion that
18 this data can tell them nothing one way or another?

19 A. Well, I -- I wouldn't quite say that. I
20 don't think a retrospective case-control study can
21 tell you nothing. What I think it can tell you is
22 there any evidence of a statistical association which
23 you might wish to follow up with another research
24 method or to try and do a further case-control study
25 which deals with some of the obvious problems in the

1 present case-control study.

2 Q. Doctor, didn't you tell the Congress of the
3 United States that this Winn Study, which you are now
4 trying to testify shows nothing about tongue cancer
5 or shows that snuff doesn't cause tongue cancer, I
6 think more particularly, didn't you testify to the
7 Congress of the United States, and I quote, "That
8 study has not even established with reasonable
9 conviction a statistical association"? You said that
10 didn't you, Doctor?

11 A. Yes, I did say that, yes, yes. I am not
12 saying that I said it.

13 Q. It went on national television all over the
14 United States, didn't it?

15 A. I didn't watch national television.

16 Q. You didn't know that you are a television
17 personality, did you?

18 A. Not until this moment.

19 Q. So, at least, at that time you told us the
20 study could tell us nothing and now you are telling
21 us that the study tells us something?

22 A. I think that's not what I said, and you are
23 taking a statement -- "Reasonable conviction" doesn't
24 mean nothing; it means that you have substantial
25 doubts about the risk estimate from this study.

1 Q. And of course that doubt would be largely
2 relieved if there had been more numbers, more victims
3 to look at?

4 A. No, only one aspect of the doubt would be
5 relieved. The aspect of the doubt would be the
6 possibility of random error. The nature of a case
7 control study is such that even if you have thousands
8 of cases, it doesn't get rid of the methodological
9 difficulty with this type of research.

10 Q. Doctor, do you know of or about Lawrence
11 Cooper?

12 A. Yes, I know both of him and about him.

13 Q. Pardon?

14 A. You asked did I know of him and about him,
15 and I said I knew both of him and about him.

16 Q. Have you met the gentleman?

17 A. No, I haven't.

18 Q. Pardon?

19 A. No, I haven't.

20 Q. Haven't read his work?

21 A. I have read some of his publications, yes.

22 Q. And have you read what he submitted to
23 Congress on this issue?

24 A. I -- I do recall reading something he wrote
25 in that issue, but again it is sometime ago and I

1 don't remember the details.

2 Q. You have not written a book on epidemiology,
3 have you?

4 A. No. I think Doctor Cooper has, though.

5 Q. Is it generally regarded as a good book?

6 A. Well, I regard it as quite a good book in
7 many ways. I can only speak for myself on that
8 particular issue.

9 Q. As you sit here, you do not recall precisely
10 what it was that the author of this book has said
11 about the Winn Study?

12 A. No, I can't quote what he said about the
13 Winn Study off the top of my head, no.

14 Q. Doctor, is this the textbook of which Doctor
15 Cooper is an author?

16 A. Yes, that's the one.

17 Q. I guess one of these days maybe you will
18 participate in writing a textbook on epidemiological
19 research maybe.

20 A. I think it is improbable, but it's not
21 impossible.

22 Q. At any rate, Doctor Cooper was also retained
23 by the smokeless tobacco industry to appear and
24 testify in front of the Congress at the same time you
25 did, wasn't he?

1 A. I don't recall, to be honest, Doctor Cooper
2 being there on that occasion. If I -- am I
3 forgetting something?

4 Q. No, I think he's submitted his report in
5 writing and you came across the water and appeared in
6 person.

7 A. That must be the explanation why I don't
8 recall him being there.

9 Q. Doctor, I want to again remind you of the
10 statement that you made in front of Congress, and I
11 want to contrast that with the statement that "Doctor
12 Cooper made in front of Congress which you just
13 alluded to. The statement you made was that Doctor
14 Winn's study does not even establish with reasonable
15 conviction a statistical association."

16 Do you recall that?

17 A. Yes, I do.

18 Q. Doctor Cooper said, "The Winn Study
19 represents the best piece of epidemiological research
20 to date pertaining to the association between snuff
21 use and oral cancer."

22 Do you agree with that?

23 A. I agree with that, yes. Yes, it is the best
24 piece of evidence.

25 Q. Then Doctor Cooper went on and said,

1 "Despite some of the problems with the Winn Study, it
2 does provide reasonably strong evidence in support of
3 a hypothesis that long-term users of snuff in
4 southern white women have an increase in lung and gum
5 cancer."

6 Do you think it provides reasonable
7 evidence?

8 A. See, the precise way Doctor Cooper put it,
9 which is a very careful considered statement, you
10 actually, if you analyze carefully, you can't fault
11 that substantially. If you --

12 Q. He says, doesn't he, sir, --

13 MR. JENNINGS: Excuse me, Mr. Braly. The
14 witness has a right to conclude his answer.

15 MR. BRALY: I'm sorry, sir.

16 THE WITNESS: Yes. If you actually read
17 what he says, "reasonably strong," it is not strong.
18 It is reasonably strong, and it supports a
19 hypothesis. He's not saying it proves anything, that
20 it is a good study, that has been done before and it
21 is reasonably strong and supports a hypothesis. Now,
22 that is a way of saying it's -- it's in his judgment
23 establishing a statistical association which supports
24 the hypothesis, but he is not saying that it proves
25 cause and effect.

1 Q. Doctor, it does say "reasonably strong
2 evidence." It didn't say weak evidence or modest
3 evidence or weak or reasonably weak. It said
4 "reasonably strong."

5 A. What I am saying is that reasonably strong
6 is not as strong as strong.

7 Q. Yes. But compared to yours, you say it
8 doesn't do anything, don't you?

9 A. No, I didn't. I said it doesn't provide, as
10 you have been quoting, evidence that gives you a
11 strong conviction or is very convincing. It's a
12 question of modifying term, reasonably strong, or
13 convincing. What we are both saying is it doesn't
14 prove cause and effect. And there are difficulties
15 associated with the study which means it is only
16 reasonably strong and not conclusive.

17 Q. At any rate, you didn't think that it
18 established even an association and he said it
19 provided reasonably strong evidence?

20 A. I think we may differ in degree --

21 Q. Yes.

22 A. -- as to how much we think this study has
23 established.

24 Q. I believe, Doctor, that you earlier defined
25 epidemiology as the study of disease by statistical.

1 methods. Do you recall saying that?

2 A. Yes, I do recall saying that, yes.

3 Q. Doctor, if the numbers had been larger in
4 the Winn Study, would the statistical strength of the
5 study have improved?

6 A. I think you would have to establish for me
7 to answer the question what you mean by "statistical
8 strength." What I mean by statistical strength. I
9 wonder if you could define what you mean by
10 "statistical."

11 Q. Well, the P value would have gotten smaller
12 or the confidence interval would have gotten smaller.

13 A. It may or may not have. If you just add
14 zeros to the numbers there, of course, the P value
15 gets smaller, --

16 Q. Sure.

17 A. -- but if --

18 Q. One would then have more certainty about the
19 results?

20 A. No, you have no guarantee it would stay the
21 same. If you have ten times as many, you know that
22 15 is going to be a hundred fifty.

23 Q. That's right. But the numbers might change
24 as they got larger?

25 A. They might.

1 Q. As a matter of fact, that sort of study has
2 been done in India where this problem is much more
3 prevalent, hasn't it, Doctor?

4 A. That sort of study. What do you mean by --

5 Q. In terms of having larger numbers of oral
6 cancer cases.

7 A. The Indian studies contain larger numbers of
8 patients. I don't dispute that.

9 Q. Are you familiar with a study by Jussawalla,
10 published in 1971, that has previously been admitted
11 in evidence in this case as Exhibit 80-J?

12 A. Yes, I know that study.

13 Q. Published in the journal, Cancer, in July of
14 1971?

15 A. Yes.

16 Q. You see, it was able to divide the oral
17 cavity into a number of different sites, wasn't it?

18 A. Yes. I thought you didn't like that.

19 Q. Well, no, actually, if the numbers are
20 adequate, I am perfectly happy, because then you
21 don't have to slice the onion so thin.

22 A. Okay.

23 Q. And when it did that, Doctor, it came out
24 with a nice solid threefold relative risk, didn't it?

25 A. Nice solid threefold risk for tongue cancer.

1 Q. Not just tongue cancer, Doctor, but tongue
2 cancer of the anterior two-thirds of the tongue,
3 Doctor.

4 A. That's what that figure says, yes.

5 Q. And it did it with a P value not of .05 or
6 .01, but a P value of .001, didn't it?

7 A. Yes. In fact, it would be given defined
8 square values, 26.3. I think you could add a couple
9 more naughts to that.

10 Q. Extremely high statistical data because of
11 the numbers involved?

12 A. Yes. Large numbers only deal with the
13 problem of chance.

14 Q. Yes. And of course this study considered
15 these people separately from the smokers because of
16 the possibility of confounding?

17 A. Indeed. Are you sure that is true?

18 Q. Yes. Chewing habit, smoking habit.

19 A. Yes, but it doesn't necessarily mean that
20 the smokers didn't chew at all.

21 Q. Of course, if that's the case, then that's
22 the way you did the data from the Winn study, because
23 you didn't factor out the smokers separately either,
24 did you?

25 A. I am merely commenting on your statement

1 that this was the chewing habit in the absence of
2 smoking and I can't actually say whether that is
3 true, because I have forgotten the fine print of the
4 study.

5 Q. Let's do a little exercise, Doctor, for the
6 benefit of the jury. You are reasonably familiar
7 with the anatomy of the oral cavity, aren't you,
8 Doctor?

9 A. Well, what does "reasonably" mean? I know
10 where the tongue is, for example.

11 Q. Did you have to learn that in order to come
12 and testify in this case?

13 A. Well, I did check with an anatomist before I
14 came.

15 Q. Let me see if you recognize anything about
16 the part of the anatomy known as the tongue.

17 A. Yes.

18 Q. Just for the sake of the drawing, allow me
19 to call this part in here the cheek and the gum,
20 although it happens to be up front.

21 A. You actually pointed under the tongue.

22 Q. No.

23 A. Behind the teeth.

24 Q. Right in here (indicating).

25 A. Oh, yes, in front of the teeth.

1 Q. Yes.

2 A. Yes.

3 Q. This would be the hard palate up here?

4 A. Yes.

5 Q. That would be the soft palate back there?

6 A. That's right, yes.

7 Q. Now, biological plausibility, Doctor, would
8 that suggest that as you smoke and the smoke goes
9 into your mouth and it has to hit the back of your
10 throat and turn around that it might increase the
11 risk for cancer back there where the smoke is
12 impinging upon the back of the mouth?

13 A. You are talking about smoking?

14 Q. Yes.

15 A. Yes.

16 Q. And of course biological plausibility for
17 cancer that is caused by the nitrosamines in snuff
18 might suggest that the risk would be higher at the
19 exact place where the quid was placed and that as the
20 juice got diffused as it went back in the mouth that
21 the risk might become smaller, wouldn't it?

22 A. That's consistent with hypothesis.

23 Certainly I wouldn't dispute that.

24 Q. Doctor, you see the line here for buccal
25 mucosa cancer?

1 A. Yes.

2 Q. If you follow it over, you get a relative
3 risk of 7.7 --

4 A. Yes.

5 Q. -- among the chewers, don't you?

6 A. Yes, --

7 Q. That's what the data says.

8 A. Let me mention with chewers. See, one of
9 the reasons that this study seems to be -- one of the
10 reasons that this study is one I have only paid some
11 attention to, one, because it is an Indian study, the
12 habit there is chewing and not snuff dipping. So the
13 relevance of this paper as it deals with a different
14 product used in a different way is something that it
15 is difficult to judge.

16 Q. Doctor, I understand you to take a
17 deposition.

18 Have you read Doctor Gupta's paper on just
19 that precise subject?

20 A. I'm not sure which paper you mean. I have
21 read several articles.

22 Q. His 1982 paper in which he considered those
23 precise issues.

24 A. I do recall reading that paper, yes.

25 Q. Do you recall where he said basically we, as

1 Westerners, have been guilty of a little cultural
2 bias by our failure to properly take into
3 consideration what has been going on in India for a
4 hundred years now?

5 A. Yes, I think I do recall him saying that,
6 yes.

7 Q. So, at least, he, who professes to be a
8 Ph.D. epidemiologist from the Johns Hopkins School of
9 Medicine on this side of the Atlantic takes the
10 position that it is that tobacco over there that is
11 causing the cancer, doesn't he?

12 A. He takes that view. I don't dispute that
13 he takes that view.

14 Q. He also testified under oath in this case.
15 Are you aware of that?

16 A. Yes, yes.

17 Q. Have you reviewed his deposition?

18 A. I have read his deposition, yes.

19 Q. I thought you probably had. So, at any
20 rate, the risk, the relative risk for buccal mucosa
21 cancer among chewers where they had a couple of
22 thousand cases, not just 250 like Doctor Winn's
23 study, but a couple thousand, was 7.7 wasn't it?

24 A. Yes, that's what this -- the figures show,
25 yes.

1 Q. I have got a red and black Doctor, but that
2 7.7, if we stuck it right there on the buccal mucosa,
3 that would be an appropriate place, wouldn't it?

4 A. No.

5 Q. It wouldn't?

6 A. No, it wouldn't.

7 Q. Well, I don't have any way I can get it
8 around to the side.

9 A. Well, that's the whole point, you see,
10 because anatomy tells me that is half a head, so it
11 doesn't contain the side of the mouth, and the buccal
12 muscosa extends from almost under your ear, right
13 around your face.

14 Q. You do consider that most of the people keep
15 it right there in the mouth, don't they?

16 A. Okay.

17 Q. He will put it right there on that side for
18 him.

19 A. Okay.

20 Q. Just so the jury will understand what I am
21 doing, I won't hide it from them. I will bring it
22 around and stick it right there, but we will all
23 understand where it is, okay?

24 A. If you like.

25 Q. Thank you. I appreciate your cooperation.

1 Now, let's look at, for instance, going back in the
2 mouth, the tongue, or the anterior two-thirds of the
3 tongue. The risk there of 3.0.; is that correct?

4 A. That's what the number says, yes.

5 Q. So can you identify the anterior two-thirds
6 of the tongue?

7 A. I imagine it would be somewhere like that.

8 Q. I will stick it right there. Okay?

9 A. (Nodding yes).

10 Q. And then, for instance, the hard palate.

11 A. Would you take that next? What about lip?

12 Q. Lip? Okay.

13 A. That's up front. Relative risk of 1.5.

14 Q. Do you want to take that? You think the
15 front lip gets the direct contact with the juice?

16 A. Well, I don't know, but I'm -- you seem to
17 be developing some anatomic progression from front to
18 back, so I would think you would start at the front
19 with the lip.

20 Q. All right. My question is was the
21 biological plausibility of the connection between
22 where the juices went --

23 A. Yes. Well, I mean I am merely following the
24 argument to see where it leads.

25 Q. Now, sir, let's look at the tongue for the

1 smokers, what was the relative risk for the tongue
2 for the smokers?

3 A. It says 1.8.

4 Q. We will stick it right there and put it in
5 black since we have got the smokers labeled in
6 black. Okay?

7 A. Yes. Then have you got one for the
8 smokers, too.

9 Q. Pardon?

10 A. Have you got one for smokers? At 1.9.

11 Q. All right. I will make one of those.

12 It looks like the lip is not a real high
13 site for cancer from any cause like that, is it?

14 A. You mean it is not supporting your anatomic
15 progression?

16 Q. No, my anatomic progression starts with
17 where the quid is located in the mouth and goes back.

18 A. Yes, but I don't mean to be unduly critical,
19 you were quite happy to put it at 7.7 on the lip
20 until I pointed it out.

21 Q. I was just doing it because it was
22 convenient. I will bring it around and put it on the
23 other side, if you want it.

24 Now, Doctor, the base of the tongue, the
25 relative risk for the chewer is what, the 2.2?

1 A. 2.2, yes.

2 Q. Somewhere down there?

3 A. Yes, in the gum. You missed the --

4 Q. Pardon me?

5 A. You missed the floor of the mouth which is
6 0.8, which is under the tongue, is 0.8. It is less
7 than one.

8 Q. And going back on the tongue, the smoking
9 goes up to 9.7, doesn't it?

10 A. Where did you get that from?

11 Q. The base of the tongue on the smokers.

12 A. Yes, on the smokers, starting there, yes.

13 Q. Going back to the soft palate, this little
14 soft thing that hangs back in the back, the smoking
15 risk right there where the smoke risk goes up to
16 12.6, doesn't it?

17 A. That's what the numbers say.

18 Q. The soft palate up there where juice
19 probably doesn't hit, it's a nice neutral 1.0., isn't
20 it?

21 A. I'm -- well, put it this way, the soft
22 palate is 1.0. The floor of the mouth is 0.8. If
23 there is somewhere that juice would collect, it would
24 be in the floor of the mouth under the tongue,
25 really, that is, if you are chewing something, when I

1 eat a chocolate, that's where most of the dissolved
2 chocolate seems to accumulate, gives a delicious
3 flavor.

4 Q. I am surprised, but I am glad you brought
5 that up, because the tobacco company in earlier
6 testimony in this case has been trying to deny that
7 the tongue would come in contact with the tobacco
8 juice. Are you now telling the jury that it does?

9 A. Oh, this chewing tobacco is not
10 snuff-dipping, which is placed between the gum and
11 cheek. I mean --

12 Q. The pan, the tobacco and lime that they use
13 in India, they wrap it up in the leaf and stick it in
14 the labial pouch, don't they?

15 A. I don't know about India, it is a different
16 product, handled a different way. This says
17 chewing. It doesn't say snuff dipping.

18 Q. It does involve tobacco in each instance,
19 doesn't it, Doctor?

20 A. That's not the only -- tobacco exists in
21 many forms with many different other substances.

22 Q. There has only been one study published that
23 purports to examine the relationship between tobacco
24 in India and all of the other factors to try and
25 filter them out; isn't that correct?

1 A. Which study are you thinking of?

2 Q. 1982 study by Doctor Gupta?

3 A. Doctor Gupta's study, yes.

4 Q. At least, his conclusions were in that study
5 that it was the tobacco?

6 A. Yes, I came to that conclusion, I don't
7 dispute but that was his conclusion.

8 Q. Thank you, sir.

9 Q. So in the one study that has been done on
10 tobacco use in the mouth that involved eight or nine
11 times as many subjects as Deborah Winn, that study
12 came to the conclusion with a high degree of
13 statistical reliability that there was a threefold
14 risk not just for cancer of the tongue, but for
15 cancer of the anterior two-thirds of the tongue,
16 right?

17 A. Yes, I just --

18 Q. Right?

19 A. Not quite, because the terms with a high
20 degree of statistical reliability is one which is a
21 bit of catchall phrase, and I would think that chance
22 is one thing, which is dealt with by P values, the
23 kinds of her test, but statistical reliability would
24 indicate -- would involve considering the quality of
25 the data, biases and confounding. Actually, because

1 I thought this was an irrelevant study, I didn't
2 review it in the detail I have reviewed Doctor Winn's
3 study.

4 Q. Nevertheless, the study did involve eight or
5 nine times as many people and it did involve people
6 who used tobacco in the mouth in an oral form.

7 A. Yes, I don't dispute that.

8 Q. And it did divide out the smokers from the
9 nonsmokers and controlled that confounding; is that
10 correct?

11 A. On the subject I'm --

12 Q. If you didn't know about that?

13 A. No, because I don't think here that it is
14 clear that the chewing habit is based only on
15 nonsmoking and the smoking habit is based on only
16 nonchewers. No, I may be wrong about that. All I am
17 saying is I can't agree with you, I don't know.

18 Q. It doesn't make a lot of difference to me
19 right now, because you said you prefer to lump them
20 together, so if you just lump them together, that is
21 the way you analyzed Doctor Winn's study?

22 A. I am not saying I prefer to lump them
23 together. You were just telling me why you thought
24 they should be kept apart and you are making a point
25 by saying they have been kept apart, so they are

1 being kept apart, perhaps your conclusions would be
2 modified in this study.

3 Q. Are you telling us they should or shouldn't
4 be kept apart?

5 A. I think it would be useful to stratify and
6 adjust for smoking habit. I don't dispute that.

7 Q. But you didn't do that in the data and the
8 numbers you presented to this jury about the tongue
9 cancers from the Winn Study, did you?

10 A. Explicitly I did, it was totally
11 unnecessary, the numbers are so comparable that, in
12 fact, there is no relative risk to adjust for smoking
13 and if you look at smoking, it -- the figure varied
14 up and down around and about one, depending precisely
15 on which cases and which controls you choose, you can
16 get relative risks that goes way down below one to a
17 little bit above one.

18 Q. What do you call a little bit above one?

19 A. Well, something in the range of one to two,
20 somewhere in that range, which in a small number --
21 or is well within the realm of chance.

22 Q. From one to 1.2?

23 A. Something in the range of one to two.

24 Q. Oh, okay. But you chose to present the
25 number of 1.1?

1 A. I didn't actually present that number.
2 There are several relative risks you can calculate,
3 depending on which cases and which controls you
4 choose. The very --

5 Q. What was the number that you gave to this
6 jury?

7 A. The one figure I gave was .74; another
8 figure that I gave was 1.1. Another figure I can
9 give I think there was one, if you choose particular
10 cases in the controls you get 1.4. But you have
11 relative risks which vary on the other side of the
12 one in no particular systematic fashion.

13 Q. If you just used the nonsmokers, so that
14 they didn't have this confounding problem for
15 smoking, can you tell the jury what that number comes
16 to?

17 A. I can answer that question very quickly from
18 my notes. I looked at that. And, in fact, when
19 you look at nonsmokers, there are only in the
20 hospital cases, 11 cases, who were dippers and
21 nonsmokers, and there were ten controls in the first
22 control, it's 11 and 10. There were five in the
23 second controls, but there were fewer than that of
24 them.

25 If you take the death certificate ones,

1 there were six dippers who were nonsmokers in the
2 cases, and four in the first controls and six in the
3 second controls. So the numbers vary by trivial
4 amounts and frankly, it is pointless to put a
5 relative risk figure on that, the groups are so
6 similar.

7 Q. Among the hospital sample, if you run that
8 calculation, isn't the relative risk about 1.5?

9 A. If you take just the hospital sample. As I
10 explained, leaving out the dead cases, produces a
11 bias. Of course, you could take the Black Hospital
12 nonsmokers.

13 Q. Excuse me, excuse me doctor. My question
14 was if you take just the hospital sample, the
15 relative risk comes out to be 1.5?

16 A. I haven't calculated as to just the hospital
17 sample.

18 Q. If you take the hospital and the death
19 cases, the relative risk comes out to be 1.45?

20 A. Where did you get the figure from?

21 Q. I ran the calculation.

22 A. You ran the calculation. I am not
23 challenging you, because I haven't run the same
24 calculation. Was it statistically significant?
25 Can I ask you a question?

1 Q. Doctor, I didn't have your computer from
2 Texas to do that, but I think as you have already
3 pointed out, the numbers when you slice the onion
4 that thin don't mean anything at all.

5 A. Okay, all right, thank you.

6 Q. So that is why I am relying on the Indian
7 study where the numbers are large for a P value when
8 I read the numbers to the statisticians?

9 A. I understand.

10 Q. I just wanted to point out that you had not
11 pointed out the smokers, and I think we have
12 established that, haven't we?

13 A. I presented all the details I'm --

14 Q. Now, Doctor, let me hand you Doctor Cooper's
15 book. I call your attention down here where he says
16 "Indeed, productive epidemiological research."

17 Do you see that sentence?

18 A. Yes.

19 Q. Would you read from that sentence.

20 A. He says "Indeed the productive
21 epidemiological research."

22 THE COURT: Sir, if you would slow down it
23 makes it difficult for him to take.

24 A. I apologize. It says, "Indeed the
25 productive epidemiological research borrows from and,

1 to a certain extent, integrates the theories of
2 several disciplines, including the biomedical
3 sciences, which includes pathology, physiology
4 microbiology, virology, immunology, and clinical
5 medicine, the social sciences, and he puts in
6 parentheses psychology, sociology, anthropology,
7 economics and political sciences and quantitative
8 disciplines, and he puts in brackets mathematics
9 statistics, demography, and operation research. Of
10 course, --" Shall I continue the next paragraph?

11 Q. Sure, read the next sentence.

12 A. Of course, all epidemiologists do not use
13 each of their disciplines to the same degree or in
14 the same manner. Is that sufficient?

15 Q. Doctor, would you take the Magic Marker and
16 go to the chart. Take your book with you.

17 A. This book?

18 Q. I would like to list some of these for the
19 jury, if you would. Theories of several disciplines
20 including the biomedical sciences. And those are
21 listing, pathology, -- would you write that down?

22 A. (Witness complies).

23 Q. And physiology?

24 A. (Witness complies).

25 Q. Microbiology?

- 1 A. (Witness complies).
- 2 Q. Virology.
- 3 A. (Witness complies).
- 4 Q. Immunology.
- 5 A. (Witness complies).
- 6 Q. Clinical medicine.
- 7 A. (Witness complies).
- 8 Q. It mentions the social sciences and starts
- 9 out by saying "psychology."
- 10 A. (Witness complies).
- 11 Q. Sociology.
- 12 A. (Witness complies).
- 13 Q. Anthropology.
- 14 A. (Witness complies).
- 15 Q. Economics.
- 16 A. (Witness complies).
- 17 Q. Political science.
- 18 A. (Witness complies).
- 19 Q. Now, over there it has one more category,
- 20 the quantitative disciplines. It mentions
- 21 mathematics.
- 22 A. (Witness complies).
- 23 Q. Statistics.
- 24 A. (Witness complies).
- 25 Q. Demography.

1 A. (Witness complies).

2 Q. And operations research.

3 A. (Witness complies).

4 Q. Doctor, you are not a pathologist, are you?

5 A. No, I am not, no.

6 Q. I could stand here and ask you to go through
7 and mark all those off that you are not, but I am not
8 going to do that.

9 A. Thank you.

10 Q. There are a couple that you are?

11 A. Right.

12 Q. One of them you have done some work in
13 psychology?

14 A. That's true, yes.

15 Q. And you have done some work in the
16 quantitative disciplines, mostly statistics?

17 A. Yes, and mathematics, too.

18 Q. And those are your areas, your principal
19 areas of expertise?

20 A. Yes, principal, I suppose, yes.

21 Q. Doctor, I take it you still take the
22 position that we don't know what causes cancer,
23 except maybe for radiation cancers?

24 A. Well, I am not putting myself forward as an
25 expert on radiation cancer, but I think the question

1 of what causes cancer is largely unresolved.

2 Q. But there are those that disagree with you,
3 aren't there?

4 A. Oh, yes, yes.

5 Q. And you were not a member of the
6 International Agency for Research on Cancer's working
7 group, were you?

8 A. No, I was not.

9 Q. But there were a large number of very
10 eminent scientists that were?

11 A. I agree.

12 Q. One of them was Doctor Gupta?

13 A. Yes.

14 Q. Others were Doctor Hoffmann and Doctor
15 Hecht, all three of which have testified in this
16 proceeding?

17 A. Yes.

18 Q. And you disagree and think that snuff does
19 not cause cancer?

20 A. Ah, --

21 Q. That's a simple "yes" or "no," doctor.

22 A. No, no, I -- I don't disagree to the
23 statement as you put it. I don't agree to the
24 statement that I'm not saying snuff does not cause
25 cancer, because you are asking me to say that I know

1 it doesn't. And of course I don't know that it
2 doesn't.

3 Q. So what you are doing is, as I hear you
4 coming into this courtroom, getting in front of this
5 jury and saying "others say snuff causes cancer, I
6 say we don't know"?

7 A. That's part of what I am saying, certainly.

8 Q. But among the others that say it does is the
9 International Agency for Research on Cancer; right?

10 A. Well, that particular group there, yes.

11 Q. Would you read to the jury beginning at the
12 top of Page 116 --

13 A. Yes.

14 Q. -- what the International Agency for
15 Research on Cancer says on this subject about snuff?

16 A. Yes. This is the section titled Evaluation,
17 and this section contains a footnote which says, "For
18 definitions of the italicized terms, see preamble."
19 So it is using quite a lot of italicized terms, which
20 they have defined elsewhere. So this first sentence
21 is that --

22 Q. Well, Doctor, let's look at those italicized
23 terms --

24 A. Yes.

25 Q. -- before we go on, if you want to. I think

1 I can find them if you will loan me the book for a
2 second?

3 THE COURT: Are you going to be a while with
4 this witness, a while longer?

5 MR. BRALY: Yes.

6 THE COURT: Let's go ahead, ladies and
7 gentlemen, and recess for the afternoon. We will
8 reconvene in the morning at 9:30, and I won't repeat
9 my admonitions to you, but remember those and we will
10 see you at 9:30 in the morning. And everyone remain
11 seated while the jury exits for the evening. Good
12 night.

13 Court will be in recess until 9:30 in the
14 morning.

15 (Court was recessed until 9:30 a.m., Thursday,
16 June 12, 1986.)
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